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Intellectual property rights and human rights

Report of the Secretary-General

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CONTENTS

		Page
Introduction		3
I.	REPLIES RECEIVED FROM GOVERNMENTS	3
A.	Brazil	3
B.	Pakistan	3
II.	REPLIES RECEIVED FROM INTERNATIONAL ORGANIZATIONS	5
A.	United Nations Conference on Trade and Development	5
B.	World Trade Organization	7
III.	REPLIES RECEIVED FROM NON-GOVERNMENTAL ORGANIZATIONS	10
A.	Center for International Environmental Law	10
B.	European Writers' Congress	11
C.	German Commission of Justice and Peace	12
D.	Greenpeace	13
E.	International Association of Audio-Visual Writers	15
F.	International Federation of Musicians	16
G.	International Publishers Association	16
H.	Max Planck Institute	17

Introduction

In its resolution 2000/7, the Sub-Commission for the Promotion and Protection of Human Rights requested the Secretary-General to submit a report on the question of intellectual property rights (IPRs) and human rights at its fifty-third session. To this end, a note verbale was sent to States, and letters were sent to international organizations and non-governmental organizations dated 6 March 2001, requesting information that would be relevant to the report. As of 29 May 2001, replies had been received from Brazil, Pakistan, the United Nations Conference on Trade and Development, the World Trade Organization, the Center for International Environmental Law, the European Writers' Congress, Greenpeace, the German Peace and Justice Commission, the International Association of Audio-Visual Writers, the International Federation of Musicians, the International Publishers Association and the Max Planck Institute. The responses are included below. Given their length and the page limitation of reports to the Sub-Commission, most of the responses appear in summary form. The originals (in English, unless otherwise noted) are available at the Office of the High Commissioner for Human Rights for consultation.

I. REPLIES RECEIVED FROM GOVERNMENTS

A. Brazil

The comments from the Government of Brazil have been included in the report of the High Commissioner on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on human rights, which is available to the Sub-Commission as document E/CN.4/Sub.2/2001/13. The report of the High Commissioner relates specifically to the right to health. As the comments of Brazil focused entirely on the promotion and protection of the right to health, they were incorporated there rather than in the present report.

B. Pakistan

1. The Government of Pakistan replied that in recent years, the international intellectual property regime has been considerably strengthened, most notably through the adoption of the TRIPS Agreement.

2. The avowed objectives in strengthening the intellectual property rights system were that it would lead to enhanced innovation, foreign investment, research and development and, indeed, transfer of technology. As stated in article 7 of the TRIPS Agreement, "the protection and enforcement of intellectual property rights should contribute to the promotion and enforcement of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

3. The experience of many developing countries with the implementation of the intellectual property agreements indicates that the fundamental objectives of these agreements are not being realized. There may perhaps be reasons to believe, at best on theoretical grounds, that in the long term, benefits could accrue in the form of increased investment, innovation and transfer of technology. However, it is painfully evident that in the short and medium term, the costs being

borne by the developing countries are higher than the gains, and that the balance between the rights holder (mostly from the developed countries) and the user of intellectual property has shifted dramatically in favour of the former. This is borne out by the following facts:

(a) There are immediate and fairly significant costs of implementing the intellectual property agreements by developing countries. These include the establishment of judicial, administrative and enforcement frameworks including the setting up of customs and border enforcement machinery;

(b) The implementation of stronger intellectual property laws is giving rise to a situation where there is a consistent increase in the prices of pharmaceutical products, software and textbooks. These products are essential to furthering the right to health, the right to education and the right to food;

(c) There are increasing constraints on acquiring technology. Patent holders can demand higher prices for transferring products and attach more onerous conditions for the use of the licence. Also, increasing the breadth and scope of patents often restricts research in areas covered by patents, most significantly in newer technology such as biotechnology;

(d) There is a lack of protection for traditional knowledge in areas where developing countries have significant assets. The increased patenting of plant varieties or of products produced from genetic resources available in the developing countries without payment of fees/royalties to local communities, whose knowledge is used in such research, is a source of concern;

(e) Stronger intellectual property rights often lead to monopolistic and anti-competitive behaviour by the rights holder with predictably negative effects on prices of products and access to technology;

(f) Higher standards for invoking restrictions on resorting to parallel imports leads to lack of flexibility for developing countries to respond and to promote genuine national interests, particularly in the areas of education and health, as was vividly evident in the recent inability of some countries to respond quickly to the emergency created by the HIV/AIDS epidemic.

4. In this context, there is a need to undertake a comprehensive review of the international intellectual property regime. The review should seek to:

(a) Restore the balance between the rights of the intellectual property holders and those of users;

(b) Ensure that the fundamental objectives of the intellectual property agreement, namely the promotion of innovation, dissemination of technology and investment, are facilitated and not hindered by the intellectual property regime;

(c) Review the intellectual property agreement with a view to introducing provisions which contribute to the development of the developing countries;

(d) Ensure that the implementation of the intellectual property agreement is not in conflict with the relevant provision of the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights.

II. REPLIES RECEIVED FROM INTERNATIONAL ORGANIZATIONS

A. United Nations Conference on Trade and Development

1. The response from UNCTAD referred to three aspects of the work of the organization relevant to protection of intellectual property (IP) - a study on the TRIPS Agreement and its development dimension, competition law and policy, and traditional knowledge.

2. In 1996, the UNCTAD secretariat prepared a report, The TRIPS Agreement and Developing Countries (UNCTAD/ITE/1). The report noted that the TRIPS Agreement represents a significant change in international standards for protecting intellectual property. Its implementation is likely to engineer fundamental changes in industrial structure, market competition and growth in many countries.

3. The main thrust of the study was that developing countries should be aware of the economic and other implications of the Agreement so that they would be able to structure their IP systems, including the implementation of the TRIPS Agreement, in a way that enhances dynamic competition and is consistent with their development objectives. Ultimately, therefore, the purpose of the study was to increase the understanding of the TRIPS Agreement in developing countries, particularly the least developed countries, and support the efforts of those countries in the formulation of strategies and the establishment of arrangements conducive to the implementation of the TRIPS Agreement.

4. Three key points arise from the report. First, the TRIPS Agreement requires substantially strengthened protection and enforcement of intellectual property rights (IPRs) in many countries, phased in over varying time periods. The strengthening of the IP regime is expected to engender positive impacts in developing countries, including more local innovation and additional inward foreign direct investment and technology transfer. However, it could also precipitate certain negative impacts, including higher prices for protected technology and products and restricted abilities to achieve diffusion through product imitation or copying. Second, in implementing the TRIPS Agreement, developing countries should aspire to strike and sustain a balance between the needs of innovative firms and their licensees for protection and easy appropriation of their intellectual property on the one hand, and the needs of legitimate follow-on competitors and consumers, on the other. Thus in accommodating their economic development goals to the TRIPS requirements, developing countries should maintain an appropriate balance between incentives to innovate and the need for adequate diffusion of technical knowledge into their economies. Third, the impact of the various disciplines of IPRs covered in the TRIPS Agreement will differ among countries depending, inter alia, on the existing IP system, the level of economic and technological development, and the mode of implementation.

5. A number of developing countries, mainly in Asia and Latin America, began the process of changing their legal regimes for intellectual property and supporting institutions in the late 1980s and early 1990s. In some countries, TRIPS will thus impose little in the way of new

obligations as countries had already initiated reforms consistent with TRIPS. For others, TRIPS requires substantial changes in norms of protection. In practice, any particular country's approach to compliance with TRIPS will depend on its own innovation strategy and technology development policies. Therefore, there remains scope for implementing the Agreement in a manner conducive to promoting dynamic competition within their own economies, allowing for appropriate legal incentives for information diffusion and local innovation. This approach would require:

(a) Establishing intellectual property right laws that are consistent with TRIPS but do not significantly disadvantage follow-on inventors and creators;

(b) Instituting incentive structures that will help stimulate innovation at the local level;

(c) Taking greater advantage of access to scientific and technical information that resides within the global information infrastructure;

(d) Applying coherent competition policies to curb the adverse effects of the abusive use of IPRs; and

(e) Improving the innovation system through broader programmes of intellectual skill acquisition and improvement of capacities to absorb new technical information.

6. The UNCTAD submission also refers to its work in the area of competition law and policy, which dates back to the early 1970s and which led to the adoption by the General Assembly (resolution 35/63) in 1980 of the Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices, in the form of a recommendation to States (the Set).

7. The UNCTAD secretariat prepared a report on competition policy and the exercise of intellectual property rights (TD/RBP/CONF.5/6) as part of the documentation for the Fourth United Nations Conference to Review All Aspects of the Set in September 2000. The Conference adopted a comprehensive resolution reaffirming the validity of the Set, calling for its implementation by States and setting down the future work of UNCTAD in this area.

8. Finally, the submission from UNCTAD referred to traditional knowledge. At UNCTAD-X, UNCTAD's member States decided to address the protection of traditional knowledge as part of UNCTAD's work in the area of trade, environment and development. In response to this mandate, UNCTAD convened in October 2000, an expert meeting on "Systems and national experiences for the protection of traditional knowledge, innovations and practices". The outcome of the meeting included recommendations.

9. In February and March 2001, the UNCTAD Commission on Trade in Goods and Services, and Commodities considered the recommendations of the meeting. The Commission made agreed recommendations to Governments, the international community and UNCTAD. It encouraged Governments, in cooperation with local and indigenous communities, to raise awareness of the role and value of traditional knowledge (TK), support the innovation potential

of local and indigenous communities, promote, where appropriate, the commercialization of TK based products and services with an emphasis on equitable benefit sharing with TK holders, and implement national legislation for the protection of TK. At the international level, the Commission recognized that the production of TK has many aspects and is being addressed in several forums, including the Convention on Biological Diversity, the World Intellectual Property Organization and the World Trade Organization. It stressed the need for continued coordination and cooperation between communities, further exchange of information on national systems to protect TK, and exploration of minimum standards for an internationally recognized sui generis system for TK protection. The Commission also made specific recommendations for UNCTAD, in particular to support coexisting work of WIPO, the World Health Organization and the United Nations Environment Programme.

B. World Trade Organization

1. The response of WTO examines human rights of individuals and public interest as traditional foundations of intellectual property protection, and looks at how they are reflected in the present multilateral intellectual property law, in particular in the TRIPS Agreement.

2. Human rights and the equitable treatment of authors and inventors, on the one hand, and public interest, on the other hand, remain the underpinnings of IP systems. While the civil law tradition might sometimes emphasize more the first approach and the common law tradition over the second approach, it would appear that these two conceptual starting-points are complementary rather than mutually exclusive. It should also be noted that the social objectives vary between different areas of IP: while modern copyright and patent laws have been designed to encourage creative work and technological innovation and provide means to finance research and development, the focus of trademark laws is more on consumer protection and in ensuring fair competition among traders.

3. The economic importance of intellectual property has grown in recent decades with the increasing role of information- and knowledge-based industries. With the increasing interdependence of national economies, it became clear that there no longer existed a functioning multilateral rule of law in this area to regulate relations and differences between countries. This led to the inclusion of IP matters in the Uruguay Round negotiations, launched in 1986, and the conclusion of the TRIPS Agreement as part of a package of agreements that make up the WTO Agreement.

4. The objectives of the TRIPS Agreement, set out in article 7, put emphasis on the public interest rationale of intellectual property protection. This article, entitled "Objectives", says that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". This corresponds with the objectives of article 15 (1) (a) and 15 (1) (b) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), which recognize the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications. It can be

argued that the TRIPS Agreement also seeks to give effect at the multilateral level to article 15 (1) (c), which establishes everyone's "right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".

5. It should be added that the TRIPS Agreement also promotes other values deemed essential for the realization of human rights. For example, the TRIPS Agreement prohibits discrimination on the basis of nationality in the area of IPRs; this is supportive of the non-discrimination principles contained in the human rights instruments. The Agreement promotes the rule of law at the national level; it requires, inter alia, the observance of due process by requiring that judicial procedures are fair and equitable, decisions are in writing and reasoned, and that parties have an opportunity to appeal. The Agreement provides for international cooperation to fight copyright piracy and trademark counterfeiting, which often have links to organized crime. The TRIPS Agreement also promotes the rule of law at the multilateral level by commonly agreed rules and peaceful settlement of disputes through a multilateral system.

6. An objective of intellectual property protection is to promote long-term public interest by means of providing exclusive rights to right holders for a limited duration of time. After the expiration of the term of protection, protected works and inventions fall into the public domain and anyone is free to use them without prior authorization by the right holder. Hence, in the long term there is no conflict but rather a mutually supportive relation between the interests of promoting creativity and innovation and maximizing access. However, during the course of the term of protection, there is potential for conflict between these two considerations, which can also mirror differences between the interest of right holders and users. The challenge of the national and international rule-maker is to find the optimal balance between various competing interests with a view to maximizing the public good, while also meeting the human rights of authors and inventors. Article 7 of the TRIPS Agreement emphasizes the need for balance.

7. An optimal balance within IP systems at the national and multilateral level can be reached by properly determining the definition of protectable subject matter, the scope of rights, permissible limitations and the term of protection. This balance is constantly developing, both at the national and international level, in response to economic and technological as well as political developments. The TRIPS Agreement is a minimum rights agreement that leaves a fair amount of leeway to member countries to implement its provisions within their own legal system and practice and fine-tune the balance in light of domestic public policy considerations.

8. Rights under article 27 (2) of the Universal Declaration and article 15 (1) (c) of ICESCR, together with other human rights, will be best served, taking into account their interdependent nature, by reaching an optimal balance within the IP system and by other related policy responses. Human rights can be used - and have been and are currently being used - to argue in favour of balancing the system either upwards or downwards by means of adjusting the existing rights or by creating new rights. Which way best serves the objectives of human rights is, at the end of the day, a matter of social and economic analysis and empirical evidence.

9. The issue of patent protection for pharmaceutical products is one where the problem of finding a proper balance is particularly acute. On the one hand, it is especially important from a social and public health point of view that new drugs and vaccines to treat and prevent diseases

are generated and the incentives provided by the patent system are particularly important in this regard. On the other hand, precisely because of the social value of the drugs so generated, there is strong pressure for such drugs to be as accessible as possible as quickly as possible.

10. The TRIPS Agreement represents an effort to find an appropriate balance between these considerations. On the one hand, the Agreement requires that, after the end of the relevant transition period, patent protection for pharmaceutical products should be available for a 20-year term of protection. On the other hand, the Agreement contains a substantial number of provisions which enable Governments to implement their intellectual property regimes in a manner which takes account of immediate as well as longer-term public health considerations. These provisions include those relating to certain exemptions from patentability, the possibility to make limited exceptions to exclusive rights, compulsory licensing, parallel importation, and the recognition that member countries may adopt measures necessary to protect public health and nutrition.

11. The issue of protection of traditional knowledge is currently being discussed by the international community, including the TRIPS Council. One of the concerns that has been expressed relates to the patenting by foreigners of traditional knowledge. Under the principles contained in the TRIPS Agreement, this should not be possible. For something to be patentable under the TRIPS Agreement, it has to be an invention which includes meeting tests of novelty and inventive step, that is to say it must not be part of what patent officials refer to as "the prior art". Traditional knowledge generally would not meet these tests. There have been cases where, improperly, patents have been granted for knowledge which turns out not to be new. In such cases, patents can be, and have been, invalidated.

12. One of the practical problems that gives rise to such improper grants of patents is that much traditional knowledge is not recorded in databases that can be consulted by patent examiners when they decide whether to grant a patent. Another concern that has been raised, especially about indigenous peoples' traditional knowledge, is that the intellectual property system does not provide sufficient opportunities for the communities to protect it from use by others. Of course, to some extent, the existing intellectual property system can help in this regard through its various fields, including the rights of authors and performers, trademarks, including certification marks, geographical indications, industrial designs, patents and trade secrets. Debate has begun as to whether the existing intellectual property system should be complemented with forms of protection more specifically directed to traditional knowledge, especially of indigenous and local communities.

13. A related topic is IP and biodiversity, in particular the relationship between the TRIPS Agreement and provisions on these matters of the Convention on Biological Diversity (CBD). The TRIPS Agreement, which deals with intellectual property, is silent on the issues addressed in the CBD of the rights of countries to regulate access to biological resources in their territories on the basis of the principle of prior informed consent and of arrangements for benefit sharing. This silence means that the TRIPS Agreement leaves Governments free to legislate in accordance with the requirements of the CBD on these matters.

III. REPLIES RECEIVED FROM NON-GOVERNMENTAL ORGANIZATIONS

A. Center for International Environmental Law

1. The Center for International Environmental Law (CIEL) has maintained a focus on intellectual property rights for a number of years. CIEL is concerned that the current international intellectual property rights regime may impact upon food security, health, development and the conservation of biological diversity, and so may undermine fundamental human rights.

2. The response of CIEL notes that as the shift to a "knowledge economy" continues, the definition of ownership and control of information becomes one of the most important policy issues facing societies. The primary justification for granting limited property rights in the form of IPRs is that they grant benefits to society by promoting innovation, creation and consumer protection. IP systems have therefore traditionally sought to strike a delicate balance between awarding private property rights to reward innovation with promoting access to the product and promoting the public interest. Increasingly, however, the balance between private and public interest is shifting. As ownership of knowledge is becoming a key determinant in defining the "haves" and "have-nots" in modern society, powerful interest groups have stepped up pressure on Governments to implement stronger international protection and enforcement of IPRs. Some groups, in particular segments of industry, have attempted to give added - and unjustifiable - force to IPRs by promoting them as natural rights without limitation; in other words, rights that have a moral force that somehow is beyond political challenge. The arguments advanced to support this position assume that a right granted over technology in one State somehow equates with a right of universal coverage. Yet, this development denies the contingent nature of IPRs - Governments may, in the interests of their citizens, choose not to grant IPRs, or to define them more narrowly. It also runs counter to a basic premise of IP systems: any increase in the strength of IPR protection should be clearly justified by associated gains in public welfare.

3. This shift in the balance between public and private interests takes on a new dimension when viewed in the international context. Developed countries - which are traditionally home to the owners of formal technology - have tended to promote IPRs as beneficial to development. At times, developing countries, by contrast - which are generally users, but not producers, of formal technology - have criticized IPRs, arguing that they raise prices and restrict access to the new technologies needed for sustainable human development. Despite bitter disputes between developed and developing countries during the Uruguay Round of trade negotiations, minimum standards for the protection and enforcement of IPRs were inserted on the international trade agenda in the form of the TRIPS Agreement.

4. As a direct result of the TRIPS Agreement, the shift in favour of IPRs-producing companies and countries has accelerated. WTO members are now obliged to introduce IP standards that in many cases increase the *scope* of IPR coverage by, for example, removing exceptions for categories of products such as pharmaceuticals; increase the *duration* of coverage; and increase the *geographical coverage* of IPRs. Members have agreed to implement IP systems that are costly and that are geared towards industrial development, but that fail to protect innovators that are knowledge rich but economically poor. Concern has also been expressed that

the TRIPS Agreement sits uneasily with the other agreements of the WTO; while the agreements on goods and services strive for trade liberalization, the TRIPS Agreement promotes intervention in the market to protect private property rights.

5. CIEL believes that, while IP protection can have positive impacts, the implementation of the TRIPS Agreement could affect negatively several matters including developing country innovation; the transfer of technology to developing countries; the transfer of technology under multilateral environmental agreements; health care and access to essential medicines; the protection of the knowledge, innovations and practices of indigenous and local communities; and the operation of certain aspects of the Convention on Biological Diversity.

6. As a first step towards resolving the complex issues raised in the TRIPS Agreement, CIEL recommends: (i) a full and public discussion by WTO members, in partnership with relevant international organizations and civil society, of the public interest issues raised by the evolving international intellectual property regime; and (ii) a systematic "sustainability review" by WTO members in the TRIPS Council of the implications of implementing the Agreement for the public interest and sustainable development, as part of the mandated review of the TRIPS Agreement.

B. European Writers' Congress

1. The European Writers' Congress applauds the affirmation of the Sub-Commission that the right to protection of moral and material interests of authors is a human right. It considers that: (i) in general, there must be a balance between the interests of individual authors and the interests of society at large; (ii) all individual creative authors should be treated equally, whatever their race, religion, or cultural, social or economic background; (iii) rights to the creative productions of indigenous communities should be respected; (iv) intellectual property rights cover a wide field of productions, some of them of an artistic nature resulting from the author's own intellectual creation and others from investment of skill, expertise or resources in industrial or commercial productions and, consequently, the respective interests in such rights are not the same in all cases; (v) the balance of the interests of individual creative authors and the interests of the society at large should be judged separately from the balancing of the interests of owners of other intellectual property rights such as patents or rights in biological productions; (vi) the provisions of the TRIPS Agreement concerning the protection of IPRs should be the subject of separate analysis and adjudication in assessing the balance between the interest of owners of these rights and the interests of the public.

2. The European Writers' Congress urges the Secretary-General to: (i) draw attention to the fact that the existence of all cultural material consisting of literary, dramatic, musical and artistic works depends upon the creations of individual authors and that the protection and sustaining of authors' rights to the greatest degree possible is therefore the major priority for the preservation and development of the cultural heritage of mankind; (ii) indicate that the Congress believes that, in serving humanity, authors should contribute to all means of ensuring the wider public dissemination and availability of their works, but that any exceptions in this area should be assessed separately from those applying to other IPRs and should be confined to certain special cases which do not conflict with the normal exploitation of the authors' works and do not unreasonably prejudice their legitimate interest.

C. German Commission of Justice and Peace

1. The German Justice and Peace Commission is analysing the negative impact of the TRIPS Agreement on the human rights to adequate food, health, and the right of peoples to freely dispose of their natural wealth and resources and not to be deprived of their own means of subsistence. The response notes that it is difficult to predict accurately the full dimensions of the effects that will result from the implementation of the TRIPS Agreement. However, the impending risks are already obvious. In addition, some developing countries are currently experiencing political pressure which involves the implementation of regulations that go beyond the TRIPS Agreement.

2. In relation to the right to adequate food, the German Justice and Peace Commission notes that according to General Comment No. 12 of the Committee on Economic, Social and Cultural Rights, the right to adequate food requires that States "ensure that enterprises or individuals do not deprive individuals of their access to adequate food". The Commission believes that the regulations concerning plant varieties provided by the TRIPS Agreement will cause considerable shifts in the seed market. The farming system of the poor rural population in the developing countries works to a large extent according to the principle of subsistence. These people are dependent on the access to means of production and seeds. They have been cultivating their seeds over centuries and exchanged them between their communities. This forms the basis for selective cultivation of positive properties. Local plant varieties have adapted themselves to the local conditions. They are highly resistant to plant diseases and climatic conditions. At least a minimum yield is guaranteed even under difficult conditions. Traditionally, the farmers have the right to retain a portion of the harvested seeds, to preserve, to refine, to use, to share, to exchange and to sell them. This is known as the farmers' right. While the TRIPS Agreement is being implemented, international seed corporations provide farmers with free supplies of seeds, which are protected by patents, and buy up local seed companies. This is happening in India. The consequences are predictable. In a few years, the farmers in the rural areas will be dependent on the patented seeds, because soon they will no longer have their own seeds and local seeds will no longer be available. Additionally, there is a risk that the number of plant varieties will decrease as a consequence of the concentration of the market. The variety of the nutritional basis will be irreversibly limited. It is obvious that the foreseeable price increase of seeds will seriously restrict the right to adequate food of those farmers who now already live at subsistence level.

3. The German Justice and Peace Commission also believes that the right to health will be affected negatively by the implementation of the TRIPS Agreement. The Commission notes that the TRIPS Agreement obliges all WTO members to provide for patents of 20-year duration in all areas of technology, including for pharmaceuticals. Developing countries are increasingly obliged to pay royalties for the use of pharmaceuticals which have been developed on the basis of their biological resources. Those who favour the TRIPS Agreement argue that only a strong regime of patent protection can motivate the pharmaceutical industry to make the high investments necessary for the development of new drugs. At the same time, it is obvious that commercial organizations do not invest in innovative and costly research projects focused primarily on the needs of the poor, because their purchasing power is very low. Patent protection in the field of pharmaceuticals will not favour the development of drugs that are mainly directed towards the needs of the poor. The cost-efficient development of drugs and the extension of public research would, however, be in the interests of the poor. In cases of national

emergency, article 31 of the TRIPS Agreement allows the use of the subject matter of a patent without the right holder giving his consent. But the recent example of pressure against South African legislation in the field of HIV/AIDS treatments shows that clarification is urgently needed. The Commission also notes that pharmaceuticals of vital necessity will get more expensive when they are subject to patent protection. As a consequence, the enjoyment of the right to health will be restricted.

4. Finally, the Commission notes that the TRIPS Agreement could reduce the right of peoples to freely dispose of their natural wealth and resources. The Commission notes article 27 of the TRIPS Agreement, which states that "... patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial applications. Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced". These obligations must be considered in connection with the basic WTO principles of national treatment (nationals and foreigners must enjoy equal treatment) and most favoured national treatment (any advantage granted by a member to the nationals of any other country shall be accorded to the nationals of all other members). This means that each country is obliged to allow the patenting of its own biological resources by foreigners. Thus, for example, in some cases, the countries of origin of genetic resources are obliged to provide patent protection even if a foreign company appropriated unlawfully the resource on which it bases the development of products or processes. These requirements in the TRIPS Agreement are not only contrary to human rights but also to the regulations of the Convention on Biological Diversity (CBD) and the International Undertaking of the Food and Agriculture Organization.

5. According to the Commission, the regulations of the CBD and the International Undertaking of the FAO are in accordance with the human right of all peoples to dispose freely of their natural wealth and resources. Consequently, they should be integrated into the TRIPS Agreement. Under them, prior informed consent for the use of genetic resources of a country is required. A company requesting a patent should give evidence of the prior informed consent of the country of origin as well as evidence of a fair and equitable benefit-sharing with that country or the community or individuals concerned. Unlawful appropriation of genetic resources by foreign individuals or companies must not be legitimized.

D. Greenpeace

1. The response of Greenpeace included a series of commentaries concerning "A patent on breeding human beings", "Patents on Life granted by the European Patent Office" and "Zoo Animals, Racehorses and People: Patents on life - a documentation of applications submitted to the European Patent Office 1999-2000". The main focus of the Greenpeace response is the European Union's Patent Directive which is currently being implemented into national legislation in Europe. According to Greenpeace, the EU Patent Directive would explicitly legalize the controversial practice of the European Patent Office of granting "patents on life". In particular, while normally patents can be granted only for inventions, not discoveries, the Directive will allow the patenting of isolated human genes - which effectively amounts only to a

discovery. This will mean that human body parts, including complete organs, mammals and large parts of living nature are to be declared the intellectual property of patent holders. Claiming extremely wide-ranging intellectual property rights over parts of living nature is becoming part of the strategy to privatize previously common goods.

2. According to Greenpeace, industry and the European Patent Office drew up the EU Directive. In addition, the genetic engineering industry exerted massive influence over the debate in the European Parliament. In order to show the extent to which industry is claiming patents on life, Greenpeace, with the support of the organization No patents on Life, carried out two years of research at the European Patent Office. More than 1,000 applications for patents from the years 1999 and 2000 were studied in detail and sorted by category. The research produced several results:

(a) There was a remarkable increase in the number of patent applications aimed specifically at human beings. Some of these patent applications prove more clearly than any other publication the extent to which the industry plans to use human beings as a new commercially exploitable source of raw material;

(b) The number of patent applications for genes is increasing dramatically and in some cases several hundred human gene sequences are claimed at once;

(c) There is a systematic extension of patents claimed in the area of food production. Today patent applications concern not only the wheat grain for sowing but also the flour made from it for baking bread;

(d) New developments comprise patent applications for non-genetically modified foodstuffs.

3. Greenpeace includes the following examples of applications for patents over life (the application numbers are included in brackets): the breeding of human embryos (WO 00/27995); a process for cloning female egg cells of zoo animals, racehorses and people before they are fertilized (WO 00/01806); artificial fertilization combined with gender determination (WO 99/33956); a procedure for testing non-genetically modified seed and the food produced from it (WO 00/48454); golden rice - rice grains with an increased Pro-vitamin A content (WO 00/53768); flour for baking bread (WO 00/29591); a claim over plants, seeds and crops with possible health-promoting ingredients and the corresponding genes, which would include the processing of the crops into food and the processed products such as sauces, ketchup or soup (WO 00/04175); over 100 gene sequences from human ovary tissue (WO 99/51727); a claim for patent protection for more than 1,000 gene sequences in a pathogen causing meningitis (WO 99/22430).

4. According to Greenpeace, following the patenting of plants, cells and organs, intervention in the genome of the human germ line has now also been patented. This breaks a taboo and abuses human dignity in an unprecedented way.

5. Greenpeace demands the following:

(a) No patents must be granted on human genes, cells, tissues, organs, or whole people; parts of people must not be degraded to commercial products; there must be no right to claim ownership of people;

(b) Life - including plants and animals - is not an invention of the gene industry and for this reason must not be patented on principle: genetic corporations must not be allowed to claim ownership rights to our common natural heritage and biological diversity;

(c) The manipulation of humans and animals must not be turned into a business;

(d) The member States of the European Patent Convention must exercise their political control and prevent the European Patent Office from granting further patents in these areas;

(e) The EU Directive on patenting biotechnological inventions should not be transposed into national law;

(f) The EU must initiate a new European patent law which prohibits the patenting of living organisms and their genes;

(g) The EU Directive should be renegotiated without delay.

E. International Association of Audio-Visual Writers*

1. The International Association of Audio-Visual Writers raised a number of issues in their response. First, they noted that the moral interests of authors, referred to in article 27 of the Universal Declaration on Human Rights, are also referred to in article 6 bis of the Berne Convention for the Protection of Literary and Artistic Works, paragraph 9 of which states: "Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honor or reputation". However, the Association notes that the strength of the protection of the moral rights of authors varies drastically from State to State.

2. The Association also notes differences of approach in the protection of authors' rights found in many civil law countries - and copyright protection - which comes from the common law. Copyright is not concerned with the interests of authors, but with the protection of works. With the object of protection being the work, protection can only be guaranteed if the work is fixed in some form. Thus, copyright law has come to an impasse with the advent of the Internet, due to the difficulty of fixing works in virtual reality. The Association also notes that the copyright system is both complex and costly, and at times inefficient. In sum, copyright protection ignores its very justification, namely the creation itself, considerably reinforces the rights of producers as opposed to authors, and confers the same prerogatives on the producer that

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* Original French.

an author has with regard to users. The continental system of authors' rights, on the other hand, permits the creator of audio-visual works a level of control that is necessary to ensure their free circulation.

3. The economic utility of copyright is identical to that of authors' rights, but while authors' rights are based on the notion of respect for the creation, copyright, which is a legal fiction, regards the producer or the production company as the sole author. The Association poses the question why copyright - which negates the link between author and work - should favour the music or film industry any more than do authors' rights (which do not negate this fundamental link).

4. Moral rights, such as those included in the continental system of protection of authors' rights, contribute to the conservation of cultural heritage. With many production companies disappearing, it is often the authors who ensure that films and other creations are preserved. The public also has an interest in ensuring that artistic creations are not damaged or destroyed. There is also the question of freedom of expression. The two rights are complementary and should be protected with equal force. Moral rights should be introduced into all IP systems and respected as inalienable rights.

F. International Federation of Musicians*

The response of the International Federation of Musicians notes that the relationship between IPRs and human rights is crucial, in particular given the emergence of new audio-visual technology at a time of globalization. The Federation notes five matters which should be considered under the present question. First, authors' rights should not be confused with IPRs that protect investments such as producers' rights, patents on medicines, trademarks, etc. Second, there has been a strong concentration of capital and commercial alliances (AOL-Warner, Vivendi-Universal-Canal Plus, Nbapster-Bertelsman, etc.) that operate particularly aggressive strategies with regard to their IPRs. Third, those who uphold the right to access information in order to gain exceptions to IPRs are serving, either directly or indirectly, the interests of the new media (Internet servers, television operators and so on), taking advantage of the confusion between information and protected creations. Fourth, article 27 of the Universal Declaration of Human Rights is constantly being violated with respect to interpretive artists in both developed and developing countries. In particular, the Federation draws attention to the failure of the last WIPO Diplomatic Conference in December 2000 to adopt an international instrument creating international norms of protection for such artists in the audio-visual domain.

G. International Publishers Association

1. IPA respectfully questions the existence of alleged actual or potential conflicts between the implementation of the TRIPS Agreement and the realization of other economic, social and cultural human rights, noted in resolution 2000/7. In particular, IPA contests the existence of such conflicts in the context of copyright protection.

2. The TRIPS Agreement in substance incorporates the Berne Convention for the Protection of Literary and Artistic Works. Both the Berne Convention and the TRIPS Agreement reflect a

balance of intellectual property rights and other human rights. As a consequence, this balance is already to a large extent incorporated within national copyright laws and can be incorporated in legislation implementing the TRIPS Agreement.

3. Consequently, the International Publishers Association makes the following recommendations. It respectfully calls on the United Nations Economic and Social Council, the World Trade Organization, the Special Rapporteurs on globalization and its impact on the full enjoyment of human rights, the United Nations High Commissioner for Human Rights, the Committee on Economic, Social and Cultural Rights, the World Intellectual Property Organization, any other competent international governmental organization and their member States:

(a) To provide wider recognition of the balance between intellectual property rights and other human rights as already enshrined in international treaties, in particular article 9 of the Berne Convention, article 13 of the TRIPS Agreement and article 10 of the WIPO Copyright Treaty;

(b) To note the differences between the relation of industrial property rights and other human rights, on one hand, and the relation between copyright and other human rights, on the other hand;

(c) To take any appropriate action to foster and to prevent actions which would impede or delay the prompt and effective implementation of the TRIPS Agreement, in particular as it relates to setting international standards for the protection and enforcement of copyright;

(d) To foster national efforts and international cooperation to supplement economic and social policies in the fields of education, science and culture.

H. Max Planck Institute

1. The Max Plank Institute stated that resolution 2000/7 gave the impression that a conflict exists between intellectual property rights and human rights. In particular, the wording of paragraph 11 seems to imply that intellectual property rights are not themselves human rights; however, the Max Planck Institute believes that at least the main kinds of intellectual property rights are human rights.

2. The relationship between intellectual property rights and other human rights is one of balance rather than conflict. The various human rights do and must complement each other. In this respect, the following remarks seem essential. Intellectual property rights have always been characterized by the search for the proper balance between authors' and inventors' rights and the public interest; for example, in the field of copyright, exclusive rights are limited in favour of the public interest, and the exercise of finding the right balance by determining the limitations of and exceptions to exclusive rights has been part of all copyright legislation since their very beginnings. The same is true for the setting of the term of protection, which is limited in time, as opposed to the duration of property rights over material objects. In addition, not all creative efforts are protected by copyright; in particular, ideas, methods, style, or mere information or news of the day are exempt.

3. Another aspect of the complementarity of intellectual property and other human rights which must not be forgotten is that exclusive rights of authors and inventors themselves have even been justified by the public interest, as may be seen from the United States Constitution of 1787 according to which the progress of science and useful arts shall be promoted "by securing for authors and inventors for limited times the exclusive right to their respective writings and discoveries". In continental law countries, authors' and inventors' rights have been justified by the philosophy of natural law, following from the idea that the results of their work are the natural property of authors and inventors.

4. Another aspect which seems essential in evaluating the relationship between intellectual property and other human rights is the fact that it is only the author's recognized exclusive rights which allow him/her to make a living from the exploitation of his/her creations. Equally, in the field of patents, it is only the recognized exclusive rights of the inventor which allow him/her to invest in research regarding, for example, new pharmaceutical products or medical procedures; without the possibility of amortizing the high cost of such research, no one would undertake to try to find new pharmaceuticals or other products which then may benefit everybody. In other words, without exclusive rights, progress in the area of medicine and other areas of invention would not take place, or at least not with comparable speed and quality. Accordingly, intellectual property promotes and makes possible the progress of science for the benefit of all.

5. Paragraphs 5 and 6 of resolution 2000/7 should be clarified to the extent that they refer to the social function of intellectual property, namely by taking into account that authors need legal protection of their rights as recognized in particular in the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights precisely because their social status is usually already quite low and they depend on the possibility of benefiting from the exploitation of their works. Following the 1967 Revision Conference on the Berne Convention held in Stockholm most parliaments of the countries concerned refused to ratify the annex which had been negotiated and which provided far-reaching exceptions to authors' rights in favour of the exploitation of works in developing countries. One of the main reasons for this rejection was that parliaments did not see any justification for making exceptions for developing countries integrating human rights obligations and principles that protect the social function of intellectual property into provisions, practices, etc. also means that the protection of authors' rights fulfils a social function, as explained above. The situation for inventors is comparable.

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ECONOMIC, SOCIAL AND CULTURAL RIGHTS

Intellectual property rights and human rights

Report of the Secretary-General

Addendum

CONTENTS

		Page
Introduction		2
I.	REPLIES RECEIVED FROM GOVERNMENTS	2
A.	Guatemala	2
B.	Mexico	11
II.	REPLIES RECEIVED FROM INTERNATIONAL ORGANIZATIONS	13
	World Intellectual Property Organization	13
III.	REPLIES RECEIVED FROM NON-GOVERNMENTAL ORGANIZATIONS	15
A.	British Copyright Council	15
B.	Quaker United Nations Office/Friends World Committee for Consultation	17

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Introduction

The present report includes responses received after the submission of document E/CN.4/Sub.2/2001/12, from the Governments of Guatemala and Mexico, from the World Intellectual Property Organization, from the British Copyright Council and from the Quaker United Nations Office/Friends World Committee for Consultation.

I. REPLIES RECEIVED FROM GOVERNMENTS

A. Guatemala

[Original: Spanish]

1. This document is a compilation of national and international legislation in the area of intellectual property, copyright and related rights in the State of Guatemala, with emphasis on those activities that are considered to be positive developments by the State in guaranteeing the exercise of such rights. Most of the information was provided by the Intellectual Property Registry of Guatemala.

2. Part I of the document describes the constitutional regime governing copyright; part II industrial property rights. Part III deals with limitations of such rights and part IV, protection of traditional knowledge, indigenous cultural values, folklore and access to biological diversity.

I. Constitutional and legal regime governing intellectual property, copyright and related rights in Guatemala

3. The Constitution of the Republic of Guatemala recognizes and protects freedom of industry and business, as well as patent rights, as rights inherent in the human person, and guarantees their holders the enjoyment of exclusive ownership of their creations, in conformity with the law and international treaties to which Guatemala is a party. Article 41 of the Constitution defines property rights and article 42, copyright and patent rights. Article 46 establishes the primacy of international law over domestic law.

4. By Decree No. 33-98 of the Congress of the Republic, which was published in the Official Journal on 21 May 1998 and entered into force on 21 June 1998, the Law on Copyright and Related Rights was adopted; it is a legislative text in the public order and in the social interest designed to protect the rights of authors of literary and artistic works, performers, phonogram producers and broadcasting organizations. This text supersedes the previous legislation, Decree No. 1037 of the Congress of the Republic, adopted in 1954, which dealt only with copyright.

5. The Law is also based on Guatemala's international obligations as a party to the Berne Convention for the Protection of Literary and Artistic Works, the International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, the Convention for the Protection of Producers of Phonograms against Unauthorized Duplication of their Phonograms and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), all of which have been adopted and ratified by Guatemala.

6. Further legislation consists of the Central American Agreement for the protection of industrial property (adopted by Decree No. 26-73 of the Congress of the Republic), and the Patent Law on Inventions, Utility Models, Designs and Industrial Designs (Decree-Law No. 153-85). However, as such laws were not considered to respond adequately to changes due to developments in international trade and new technologies, the Industrial Property Law was enacted. It contains a series of norms effectively recognizing industrial property rights and protecting them in accordance with the requirements of today.

7. The need to revise earlier legislation in this field was also obvious in view of Guatemala's interest in strengthening protection of the intellectual property rights laid down in the Universal Declaration of Human Rights and in two provisions incorporated into the 1985 Constitution of the Republic concerning the protection of such rights: the first indicating that copyright is a fundamental human right and that those holding such rights enjoy exclusive ownership of their work in accordance with the law and international treaties (art. 42) and the second, that treaties and conventions ratified by Guatemala take precedence over internal law (art. 46). The incorporation of these two provisions into the Constitution, therefore, raised the need for the State to provide better and more effective protection of such rights, as a basic principle of social justice.

8. After the Law on Copyright and Related Rights had been in force for more than two years, experience with its implementation highlighted the need to expand, clarify and in some cases correct some of its provisions, not only to provide authors and right-holders with genuine and effective protection of such rights, but also to make the Law more responsive to current requirements imposed by the new technologies available for the dissemination of works. For this reason, the executive branch sponsored the adoption of a set of amendments to the Law; they are contained in Decree No. 56-2000 of the Congress of the Republic, which was adopted on 31 August 2000 and entered into force on 1 November 2000.

9. The above-mentioned Law grants authors a series of rights of a moral nature (right to be mentioned as author, right to ensure that the work is not altered or changed, etc.) and proprietary nature (right to authorize third parties to reproduce, distribute and market the protected work, communicate it to the public in any form whatsoever and make any use of it whatsoever); establishes exceptions to these rights (private copy, library copy, right of citation, etc.), fixes at 75 years the time limit for the protection of all categories of works with regard to property rights; establishes special provisions protecting computer programmes as literary works; includes a group of provisions governing audiovisual works and provides appropriate regulations for the different contracts covering such rights.

10. Principally, however, the reforms recently adopted by the Congress of the Republic will put into effect a new system of organization, operation and supervision of collective management societies; a series of detailed rules for injured parties to obtain provisional measures, including so-called border measures, through judicial channels; measures to apply oral proceedings, as governed by the Civil and Commercial Code of Procedure, to civil actions and the possibility, when the parties so agree, of submitting disputes to alternative dispute-resolution procedures, in conformity with the Arbitration Law currently in force.

11. In the area of criminal justice, the Law enables injured parties to associate themselves with criminal proceedings in the case of offences against copyrights and related rights, and also lays down an obligation for the Office of the Attorney-General of the Republic to establish a special unit with exclusive responsibility for the investigation and prosecution of offences against intellectual property rights.

II. Constitutional and legal regime governing industrial property rights in Guatemala

12. Like the rights of authors, the rights of inventors are recognized as being fundamental human rights by the Constitution of the Republic, which states that those holding such rights enjoy exclusive ownership of their invention in accordance with the law and international treaties (art. 42). Similarly, article 46 of the Constitution states that, in matters of human rights, treaties and conventions accepted and ratified by Guatemala take precedence over internal law. Mention should also be made of other fundamental provisions closely linked, directly or indirectly, with industrial property rights, stating, for example, that the economic and social system of the Republic is based on the principles of social justice (art. 118); that it is the fundamental duty of the State to promote the economic development of the Nation by stimulating enterprise in agriculture, livestock raising, industry, tourism and other activities, to protect consumers and users as regards preservation of the quality of domestic consumer products and export products and to create appropriate conditions for promoting the investment of domestic and foreign capital (art. 119 (a), (i) and (n)).

13. A joint effort which began in late 1999 involving the Ministry of the Economy, the Intellectual Property Registry, the World Intellectual Property Organization (WIPO), the Permanent Secretariat of the General Treaty on Central American Integration (SIECA) and representatives of various private sectors, focused on the adoption by the Congress of the Republic of a law governing intellectual property. The new law would bring together all provisions governing the acquisition, protection, entry into effect and cessation of rights over marks and other distinctive signs, inventions, utility models and industrial designs, would define and lay down regulations for the repression of unfair competition (including the protection of industrial or trade secrets) and would also establish procedures for implementing effective measures of protection against violations of industrial property rights.

14. That process culminated in the adoption on 31 August 2000 of the Industrial Property Law, Decree No. 57-2000 of the Congress of the Republic, which entered into force on 1 November 2000. The following are the main features of the Law:

In the area of marks and distinctive signs, it provides regulations protecting so-called well-known marks, a category that had previously not been adequately treated under Guatemalan legislation;

It provides for the possibility of registering three-dimensional marks and of requesting the cancellation of a domain name when it corresponds to a distinctive sign and its use may cause confusion or a risk of association in the mind of the consumer;
It provides regulations for registering collective marks and certification marks;

It provides for the possibility of opening a registry of appellations of origin, as a subdivision of geographical indications, but exclusively of appellations originating in Guatemala, ownership over which shall be assigned to the State, with the possibility for the administrating body, in which the Intellectual Property Registry participates, to authorize its use by third parties, in accordance with the specific rules and regulations to be adopted in each case;

In the area of patents, it makes provision, for the first time, for protection of plant varieties, pharmaceuticals and agricultural chemicals, previously excluded from this type of protection;

It establishes regulations for the protection of utility models and industrial designs;

It contains a group of provisions governing unfair competitive practices, in particular those relating to trade secrets and violations thereof, including undisclosed information and test data provided to the administrative authority for the purpose of obtaining medical licences prior to marketing pharmaceuticals and agricultural products;

In all categories of rights covered by the new Law, provision has been made for modern and expeditious registration procedures enabling applicants to obtain registration promptly;

The Law contains a series of regulations for the enforcement of industrial property rights which include the possibility for injured parties to obtain provisional measures, including so-called border measures; the establishment of oral proceedings for civil claims for compensation and the possibility, if the parties involved so agree, of submitting disputes to conflict-resolution procedures pursuant to the Arbitration Law;

In the area of criminal justice, the Law enables injured parties to associate themselves with criminal proceedings in the case of offences against intellectual property rights and lays down an obligation for the Office of the Attorney-General of the Republic to establish a special unit with exclusive responsibility in the area of intellectual property, similarly, the characterization in the Penal Code of offences against intellectual property rights is brought into line with the provisions of the Law.

III. Limitations of rights

15. As intellectual property rights, like all rights, are not absolute, the new Guatemalan legal regime provides exceptions for each category of rights, to permit an appropriate balance between the legitimate interests of holders and the vital interests of the community.

16. The Industrial Property Law provides explicitly for cases in which the exclusive rights granted to holders may not be invoked to challenge acts by third parties without prior authorization. Such cases are specified in the provisions below.

17. In the area of marks, the Industrial Property Law stipulates the following:

(a) The registration of a mark does not grant the right to prohibit a third person from using the following in relation to products or services legitimately placed on the market: (i) his name or address, or those of his trade establishments; (ii) indications or information about the characteristics of his products or services, including their quantity, quality, utilization, geographical origin or price and (iii) indications or information about availability, utilization, application or compatibility of his products or services, in particular with regard to spare parts or accessories. This limitation shall apply provided the product is used in good faith and there can be no confusion regarding the trade source of the products or services involved (art. 36);

(b) The registration of a mark does not give its holder the right to prevent the free movement of products that bear it legitimately and have been introduced into the market, in the country or abroad, by that holder or by another person having the holder's consent or economic ties with the holder, provided the products and any packaging that has come into immediate contact with them have undergone no modification or deterioration (art. 37);

(c) When the mark consists of a label or other sign composed of a series of names or graphic elements, protection will not include those names or graphic elements which are in general use or necessary in a trade context (art. 38).

18. In the area of patents, the Industrial Property Law stipulates the following:

(a) The following may not be protected by patents: (i) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (ii) an invention whose use would be contrary to public order or morality, it being understood that such use will not be considered contrary to public order or morality solely because it is prohibited, limited or made subject to conditions by a legal or administrative provision and (iii) an invention whose commercial use is necessary to preserve the health of humans, animals, plants or the environment (art. 92);

(b) When the patent protects a plant, animal or other organism capable of reproduction, the holder may not prevent third parties from using that entity as an initial basis for obtaining new viable biological material and marketing the material thus obtained, except where repeated use of the patented material would be required in order to obtain such material (art. 129, para. 3);

(c) When the patent protects a plant or animal or its reproductive or multiplication material, the holder may not prevent the use of the product obtained from the protected plant or animal for subsequent reproduction or multiplication by a farmer or stockbreeders, and the marketing of that product for agricultural use or consumption, provided the product has been obtained on the farmer or stockbreeder's own holding and that the reproduction or multiplication is performed on the same holding (art. 129, para. 4);

(d) The patent shall not entitle the holder to prevent: (i) acts performed in the private sphere and for non-commercial purposes; (ii) acts performed exclusively for purposes of experimentation concerning the subject of the patented invention; (iii) acts performed

exclusively for purposes of teaching or scientific or academic research, for non-commercial purposes, concerning the subject of the patented research and (iv) acts referred to in article 5 ter of the Paris Convention for the Protection of Industrial Property (art. 130);

(e) The patent shall not give the right to prevent a third party from conducting trade negotiations concerning a product protected by the patent or obtained through a patented procedure, after that product has been placed on the market in any country by the holder of the patent or by another person having the consent of or economical ties with the holder (art. 131);

(f) When the patent protects biological material capable of reproduction, the patent shall not cover the material obtained through the multiplication or propagation of the material introduced into the market in accordance with paragraph 1, provided that the multiplication or propagation is a necessary result of the use of the material in conformity with the purposes for which it was introduced into the market, and that the material deriving from such use is not used for purposes of multiplication or propagation (art. 130, last para.);

(g) In the public interest and in particular for reasons of national emergency, public health, national security or non-commercial public use, or in order to correct an anti-competitive practice, the Registry may stipulate the following at any time, at the request of the authority or an interested person and after hearing the person concerned: (i) that the invention that has been patented or in respect of which a patent has been applied for shall be used for industrial or business purposes by a State agency or by one or more public or private legal entities designated for that purpose; or (ii) that the invention that has been patented or in respect of which a patent has been applied for shall remain open to the granting of one or more obligatory licences, in which case the competent national authority may grant a licence to anyone who requests one, subject to the conditions established (art. 134).

19. In the area of copyright, the Law on Copyright and Related Rights stipulates:

(a) Works protected by this Law may be communicated lawfully, without the authority of the author or payment of any remuneration being necessary, where the communication: (i) occurs in an exclusively domestic environment, provided that no direct or indirect economic interest exists and that the communication is not deliberately disseminated outside by any means, either entirely or in part; (ii) is made for exclusively educational purposes in the course of the activities of a teaching institution by the staff and students of the said institution, provided that the communication has no direct or indirect profit-making purpose and the public consists solely of the staff and students of the institution or parents or tutors of students and other persons directly connected with its activities and (iii) is essential for the conduct of a legal or administrative proceeding (art. 63);

(b) With regard to works already disclosed, the following is likewise permitted without the authority of the author: (i) the reproduction by reprographic means of articles or short excerpts from lawfully published works for teaching or the holding of examinations at educational institutions, provided that there is no profit-making purpose and the use does not interfere with the normal exploitation of the work or prejudice the legitimate interests of the

author; (ii) the individual reproduction of a work by a non-profit-making library or archive where the copy is in its permanent collection, for the purpose of preserving the said copy and replacing it in case of need, or alternatively for the replacement of a similar copy in the permanent collection of another library or archive where that copy has been mislaid, destroyed or rendered unusable, provided that it is not possible to acquire the copy in a reasonable time, or on reasonable terms; (iii) the reproduction of a work for the purpose of judicial or administrative proceedings and (iv) the reproduction of a work of art on permanent display in a public place, or on the outer wall of a building, such reproduction being done in a medium different from that used for the making of the original, provided that the name of the author, if known, the title of the work, if available, and the place in which it is located are specified (art. 64);

(c) It shall be permissible for the lawful copy of a work expressed in writing to be lent to the public by a library or archive whose activities have no direct or indirect profit-making purpose (art. 65);

(d) It shall be lawful, without the authorization of the owner of the rights and without payment of remuneration, on condition that the source and the name of the author of the work used, if given, are mentioned: (i) to reproduce and distribute information, news and topical articles in the press, or disseminate them by broadcasting or cable distribution, provided that such reproduction, broadcasting or transmission to the public has not been expressly reserved; (ii) to reproduce and make available to the public in connection with information on current events, by means of photography, videograms, broadcasting or cable transmission, fragments of works seen or heard in the course of the said events, to the extent justified by the informatory purpose; (iii) to make use, by any means of communication to the public, for the purposes of imparting information on current events, of political or judicial speeches, dissertations, addresses, sermons and other similar works delivered in public, provided that the authors thereof shall retain the exclusive right to publish them for other purposes; (iv) to include in one's own work fragments of the works of others in written, audio or audiovisual form, and also three-dimensional, photographic and other similar works, provided that the said works have already been disclosed and that they are included by way of quotation or for analysis in connection with teaching or research (art. 66);

(e) Lectures or courses given at teaching establishments may be freely annotated and collected, but their publication or reproduction, whether total or partial, is prohibited without the written authority of the person who delivered them (art. 67);

(f) The publication of laws, decrees, regulations, ordinances, agreements, resolutions and the decisions of courts and administrative bodies, and also official translations of such texts, may be done freely insofar as the official publication is adhered to (art. 68);

(g) The publication of the portrait or photograph of a person shall be free only for information, scientific, cultural or teaching purposes or where it is connected with events or circumstances in the public or social interest, provided that the prestige or reputation of the person is not thereby diminished and that the publication is not contrary to morality or proper practice (art. 69);

(h) The performance of phonograms and the receiving of radio or television broadcasts shall be lawful where it is done for the purposes of demonstration to customers in business establishments that display and sell receiving, reproduction or other similar apparatus or audio or audiovisual media that embody the works used (art. 70);

(i) Broadcasting organizations may, without the authority of the author or payment of special remuneration, make ephemeral recordings of a work that they have the right to broadcast, using their own equipment and for use in their own broadcasts. Nevertheless, the broadcasting organization shall destroy the recording within a period of six months from its making, except where a longer period has been agreed with the author. The recording may be preserved in official archives where it possesses exceptional documentary character (art. 71).

IV. Protection of traditional knowledge, indigenous cultural values, folklore and access to biological diversity

20. The intellectual property regime of Guatemala contains no provisions governing the protection of traditional knowledge, indigenous cultural values, folklore and access to biological diversity, but draft legislation in this area is expected to be enacted shortly.

21. There are, however, other legal provisions which lay down regulations for certain aspects relating to those areas.

22. The Constitution of the Republic lays down the following basic norms:

(a) The right of persons and communities to their cultural identity, in accordance with their values, their language and their customs, is recognized (art. 58);

(b) National artistic expression, popular art, folklore and indigenous handicrafts and industries, must be given special protection by the State in order to preserve their authenticity. The State shall foster the opening of national and international markets in order to ensure a free market for the work of artists and handicraft workers, and it shall promote their training and professional and financial advancement (art. 63);

(c) The conservation, protection and improvement of the natural heritage of the Nation is declared to be in the national interest. The State shall encourage the establishment of national parks and nature reserves and sanctuaries, which shall be inalienable. A law shall guarantee their protection and the protection of the fauna and flora they contain (art. 64);

(d) Guatemala is made up of different ethnic groups, including indigenous groups of Mayan ancestry. The State recognizes, respects and promotes their ways of life, customs, traditions and forms of society, the wearing of indigenous costumes by men and women, languages and dialects (art. 66). In this connection, the Law on Copyright and Related Rights, Decree No. 33-98, stipulates that expressions of folklore belong to the cultural heritage of the country and shall be provided for in specific legislation (art. 14);

(e) The State, the municipalities and the inhabitants of the national territory shall be obliged to foster social, economic and technological development aimed at preventing contamination of the environment and maintaining ecological equilibrium. The necessary standards should be laid down to ensure that the fauna, flora, land and waters are used and developed rationally and not plundered (art. 97);

23. The following instruments are also in force in Guatemala:

(a) Law on the Protection and Improvement of the Environment (Decree No. 68-86 of the Congress of the Republic), which aims at ensuring ecological equilibrium and the quality of the environment to improve the quality of life of the country's inhabitants. Its specific objectives are: the protection, conservation and improvement of natural resources; restoration of the environment and prevention of its misuse; prevention, regulation and control of causes of environmental deterioration and contamination of ecological systems; design of educational, environmental and cultural systems; environmental policy design; promotion of appropriate technologies, etc.;

(b) Law on Protected Areas (Decree No. 4-89 of the Congress of the Republic). This law was promulgated for two specific purposes: (i) introduction of regulations for the use, handling and conservation of the country's wildlife resources; (ii) establishment of the Guatemalan System for Protected Areas;

(c) Decree No. 20-76, establishing the Exclusive Economic Area, and the Law on Animal Health (Decree No. 463 of the Congress of the Republic) represent ordinary legislation applicable to this field.

24. Similarly, the Convention on Biological Diversity was adopted on 21 February 1995 by Decree No. 5-95 of the Congress of the Republic, ratified on 14 June 1995, and its instrument of ratification deposited with the United Nations on 10 July 1995. The objectives of the Convention, which was elaborated at the Earth Summit held in Rio de Janeiro in June 1992, are the conservation of biological diversity, the sustainable use of resources and the sharing of the benefits arising out of their use.

25. The Peace Agreements contain provisions relating to the environment, natural resources and sustainable development, including the following:

(a) Indigenous communities are recognized as having the right to their traditional practices with regard to the use of natural resources;

(b) The use of customary law in indigenous communities for managing their internal affairs, principally as regards their natural heritage, is validated and tacitly accepted;

(c) The Guatemalan nation is defined and characterized as being of national unity, multi-ethnic, multicultural and multilingual;

(d) Provision is made for economic and social policies to be designed and implemented, based on sustainability, to achieve an increase in the country's total productivity (with special emphasis on the areas of ecotourism, forestry and fishery resources) for the sectors of the population which are currently in a situation of poverty.

B. Mexico

[Original: Spanish]

1. The Convention on Biological Diversity is an example of progress in international law in the establishment of norms of protection to address the new problems arising from technological advances and developments in natural resource exploitation.

2. Trends in human rights have led to a movement for the recognition of the collective rights of indigenous peoples and communities, and they in turn have demanded rights over the natural resources in their territories.

3. Indigenous peoples have a relationship of respect and care with natural resources, and they have developed a wealth of traditional knowledge. As a result, their territories are ones of great biological diversity.

4. Indigenous peoples and communities did not consider it necessary to patent or register such knowledge, resources or practices. On becoming aware of the many forms of appropriation of their territories, including their traditional knowledge, they have demanded that their territories and knowledge be respected and that they themselves be taken into account in the elaboration of rules for the protection of their own technologies.

5. With regard to intellectual property and human rights, it should be noted that States do not recognize indigenous peoples as having rights that are a priori inalienable, hence as parties to the Convention on Biological Diversity. Thus there is no recognition of the relationship between indigenous peoples' lands and territories, their knowledge and biodiversity.

6. Despite the fact that indigenous peoples are recognized by the Convention, it establishes no mechanisms for their participation. Similarly, the Convention does not attach importance to action to combat biopiracy or indigenous peoples' lack of control over the genetic resources in their lands and territories, including marine areas. Finally, it shows obvious favouritism for current international, multilateral, bilateral and national legal frameworks, including intellectual property regimes and their impact on indigenous knowledge, and fails to connect article 8 (j) and others to various international instruments dealing with indigenous rights.

7. The Instituto Nacional Indigenista proposes the following in order to give effect to resolution 2000/7:

(a) Elaboration of mechanisms to ensure the effective participation by indigenous peoples in the implementation of article 8 (j) of the Convention on Biological Diversity and related articles through the following:

(i) Recognition of indigenous peoples as parties to the Convention;

(ii) Adoption of the recommendation of the second international indigenous forum regarding the establishment of a working group on indigenous populations;

(iii) Involvement of indigenous peoples in the interpretation of article 8 (j) and related articles, including legislative reforms in this area, environmental plans of action and impact studies;

(iv) As a matter of urgency, promotion of the right to prior informed consent in all mechanisms designed to ensure participation by indigenous peoples;

(b) Development of mechanisms and processes to ensure indigenous peoples' control over their lands and territories for the protection and improvement of their biodiversity;

(i) Recognition of the a priori inalienable rights of indigenous peoples;

(ii) Recognition of the relationship between indigenous peoples' territories and lands and their knowledge, innovations and practices in relation to biodiversity;

(iii) Recognition of their right to demarcate their lands and territories;

(c) Development of mechanisms for ensuring the participation of indigenous peoples in the process of incorporating the sustainable use of their resources, procedures and practices, provided they have first given their informed consent, into development plans, policies and processes at national and international level, with special attention to cross-border topics of importance to indigenous people;

(d) Elaboration of practices for the prevention of biopiracy, monitoring of bioprospection and access to genetic resources;

(i) Moratorium on all bioprospecting and/or collection of biological material in indigenous peoples' territories and in protected areas, as well as the issuance of patents based on such collection, until such time as a system of protection is established;

(ii) Recognition of indigenous people's rights to access to and repatriation of genetic material held in all ex situ collections, such as gene banks, herbalist shops and botanical gardens;

(e) Distribution of the benefits deriving from the use of indigenous knowledge in accordance with other rights, obligations and responsibilities, such as land rights and the right of indigenous people to manage their own culture, in order to facilitate the transmission of knowledge, innovations, practices and values to future generations.

II. REPLIES RECEIVED FROM INTERNATIONAL ORGANIZATIONS

World Intellectual Property Organization

1. WIPO believes that both the human rights and the intellectual property communities would be best served by a technical and accurate analysis of the relationship between intellectual property rights and human rights which refers to specific cases. WIPO remains willing to contribute its expertise on intellectual property to discussions of this nature.

2. The relationship between intellectual property and human rights has received little attention. It was in recognition of this that WIPO, in cooperation with OHCHR, organized the successful panel discussion on intellectual property and human rights on 9 November 1998.

3. Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) protects both the human right of authors to benefit from the moral and material interests resulting from their literary, artistic and scientific productions, and the human right of the public to have access to productions protected by the author's rights. The two rights are formulated and juxtaposed in a similar way in the Universal Declaration.

4. The right to the use and dissemination of information - the freedom "to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits" - and the right to protect the creators of information - the "moral and material interests resulting from any scientific, literary or artistic production of which he is the author" - may at once be both complementary and competing. Realization of the former rights may depend upon the promotion and protection of the latter rights; on the other hand, exercise of the latter rights may, in certain circumstances, appear to hinder or frustrate realization of the former rights.

5. The tension is, however, the antechamber to a larger debate on the relationship between IP and the realization and promotion of other human rights in ICESCR and the Universal Declaration, such as the rights to health, adequate food and education, as well as the right to development.

6. Resolving tensions and striking balances is, however, not unfamiliar to the IP system. All IP rights are subject to various exceptions and limitations, and in some cases compulsory (non-voluntary) licences, tools which can be used to strike the right balance between the rights of creators and those of users. These limitations can resolve tensions internal to intellectual property and external to other systems - such as human rights.

7. International IP standards provide for legal measures that may be adopted in national laws to balance the rights and interests of rights-holders and the public. These measures permit national authorities to craft their IP laws in line with their respective economic, social, technological and cultural developmental goals.

8. For example, in the field of patents, these measures enable national laws to exclude from patentability what would otherwise be patentable subject matter or to restrict patent rights, on grounds such as the protection of human, animal or plant life and health, prejudice to the environment, morality and the ordre public.*

9. More generally, article 8 of the TRIPS Agreement provides that:

> "1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
>
> "2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

10. In addition, national laws can authorize compulsory licensing under certain conditions (as set out in article 31 of the TRIPS Agreement) and measures can be adopted to control anti-competitive practices in contractual licenses (see article 40 of the TRIPS Agreement).

11. However, these are enabling provisions only, and their precise scope, meaning and effect in practice are subject to the interpretation and implementation of national lawmakers.

12. The possibilities created by the provisions are not, however, unlimited and should not be interpreted so broadly as to negate the underlying fundamental goals and advantages of the IP system. The patent system, for example, encourages people to invent. Granting exclusive rights to an invention for a limited period of time, in particular to those engaged in commercial enterprises, encourages them to invest the resources necessary to make and commercialize the inventions. The patent system also encourages people to disclose inventions, rather than retain them as trade secrets. It should also be borne in mind that new inventions, by definition, do not take away from the public what the public already had. Inventions have to be new, which means different from what existed before.

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* See, for example, article 27 (2) of the TRIPS Agreement, "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

13. Similarly, in the field of copyright, national legislators may take advantage of certain exceptions and limitations which are, however, not designed to undermine the fundamental principles of the copyright system.

14. All human rights are interdependent and indivisible. The Vienna Declaration and Programme of Action (1993) adopted at the World Conference on Human Rights notes that "(a)ll human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally and in a fair and equal manner, on the same footing and with the same emphasis".

15. Tensions between various human rights are not uncommon and balances must be struck all the time. For example, tensions between the right to freedom of speech and the right to privacy and to dignity are well known.

16. Thus, IP laws do not vest authors and inventors with absolute and unrestricted rights, as is sometimes suggested. For example, resolution 2000/7 adopted by the Sub-Commission on the Promotion and Protection of Human Rights on 17 August 2000 affirms that IP is a human right "subject to limitations in the public interest". Such statements appear to pass over the complementarity of interests that authors/inventors and the wider public have in an IP system and the system's built-in limitations, exceptions to the system and the tools that can be used to find the right balance.

17. Of course, there may always be legitimate disagreements over what constitutes the "right balance". What constitutes the right balance depends largely upon one's perspective. Just as with a conflict that may exist between, for example, the rights to freedom of speech and to privacy, there is often no single right answer, but as many perspectives as there are affected constituencies. Implicit within the notion of "balance" is a compromise in which as many competing interests as possible are satisfied as far as possible. The IP system allows lawmakers certain flexibilities and options to meet their respective developmental goals, and in so doing the opportunity to strike the right balance.

III. REPLIES RECEIVED FROM NON-GOVERNMENTAL ORGANIZATIONS

A. British Copyright Council

1. The British Copyright Council is an association of bodies representing those who create, or hold interests or rights in literary, dramatic, musical and artistic works, and those who give performances, or hold rights or interests in performances, being works and performances in which rights subsist under the United Kingdom Copyright Designs and Patents Act (1988) as amended.

2. The British Copyright Council supports the resolution in principle but would emphasize three matters.

3. The first refers to the relationship between intellectual property and industrial property. At one time, industrial property (patents, designs, trademarks and so on) and copyright (intellectual property) tended to be treated separately. Industrial property came

under the umbrella of the Paris Convention (1883) as revised and copyright under the Berne Convention (1986) as revised. The underlying justifications for these types of right differed in some respects, as indeed did the rationales for different types of industrial property, for example as between patents and trademarks. Today, it is much more common for the term intellectual property to be used generically to cover all rights in this area. For example, the Trade-Related Aspects of Intellectual Property Agreement (TRIPS) covers virtually all areas of intellectual property, and indeed the generic term is not used by the World Intellectual Property Organization, which is responsible for much of the international developments in intellectual property. However, it must be borne in mind that, whilst there may be some conceptual similarities between the different branches of intellectual property, there are also important differences. It does not necessarily follow, in human rights matters as in other areas, that the approach should always be the same. Thus, any evaluations of patents or trademarks do not automatically or necessarily apply to copyright.

4. The second issue relates to the balance between copyright as a property rights and the protection of the public interest. Creators of copyright works and related subject matter have rights which are recognized and guaranteed by article 27 of the Universal Declaration on Human Rights. They are fundamental private property rights. However, they are not absolute: there are various control mechanisms built into this area of law to ensure that an appropriate balance is maintained between private property and the public interest, for example, to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancements and its benefits, as identified in article 27 (1) of the Universal Declaration.

5. Thus, the scope of copyright protection is limited and does not provide control over the ideas, information or concepts expressed in such works. Further, all jurisdictions have various built-in public interest exceptions and limitations permitting some uses of works without consent.

6. However, limitations upon the private property rights of creators cannot go too far without undermining the very essence of the property rights. Many international conventions, alive to the need to ensure that the balance does not tilt unfairly against authors, performers and related right-holders, thereby, in effect, resulting in the expropriation of fundamental private property rights, now contain a so-called three-step test. For example, article 13 of the TRIPS Agreement provides that member States shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right-holder.

7. Thus, while in general, copyright comprises a set of exclusive rights, there are opportunities to modify them by, on occasion, allowing free use of copyright works, or use in exchange for fair compensation; but all such modifications are subject to the three-step test. This has been the approach taken, for example, in the recently adopted European Directive on Copyright and Related Rights in the Information Society (May 2001).

8. It may be that the exceptions and limitations to exclusive private property rights of copyright holders, within the terms of the three-step test, do not always satisfy the needs of those in developing countries, for example, who require access to works for education, research or similar purposes but cannot afford to meet the legitimate royalties required for their use. The

solution to this difficulty cannot be to expropriate the private property rights of creators of such material in breach of article 27 (2). Rather, it must be a matter for Governments to determine whether and how they can provide economic assistance so that copyright works can be made available in those societies. There is an important distinction between the human rights implications of expropriating private property for desirable social purposes and of protecting such rights, but providing those who seek to use such works, from whatever source, with the means of paying for them.

9. The third issue relates to the situation where copyright is not given adequate protection. The rights of creators, as recognized in article 27 (2) of the Universal Declaration, are still in need of full legislative recognition, practical application and enforcement in many jurisdictions, including those which make the greatest use of the works of creators. Many creators passionately believe their moral rights in their creations to be as important, if not more important, than their economic (material) rights. However, moral rights are still not expressly provided for in some countries. Where there is express provision, the rights are sometimes inadequately expressed or are limited in scope. There are also too many opportunities for those exploiting the works of creators to nullify or minimize the moral rights protection provided for in legislation by the use of general waiver provisions and other devices. Today, in our digital society, the opportunities to interfere with and distort the works of authors and performers are greater than ever before (as implicitly acknowledged by article 5 of the WIPO Performances and Phonograms Treaty, 1996). It is increasingly important to ensure that moral rights are effectively protected and to limit the opportunities for those using the works of creators to unreasonably avoid their application.

B. Quaker United Nations Office/Friends World Committee for Consultation

1. Intellectual property rights should not be considered as human rights. Rather they are instruments used by societies to achieve social and economic goals. They may indeed be a means - but not the only means or necessarily the best means - of fulfilling the obligations of article 27 of the Universal Declaration to reward human creativity. The means of fulfilling human rights obligations should not be confused with the human rights themselves. Indeed, there is considerable debate about how different IPRs and the way they are implemented affect a wide range of human rights referred to in other articles of the Universal Declaration.

2. Moreover, it seems that human rights should apply to natural persons, not legal persons. IPRs are private rights, under TRIPS, which may be exercised or held by natural or legal persons. According to various inputs we have had in our work, IPRs are increasingly used by corporate bodies as part of their asset portfolio and investment protection mechanisms - not as a means of supporting human rights. Indeed, it might be helpful to re-think the language used to describe IPRs and call them instead intellectual property privileges, which is what they are, and thus remove the possible confusion with human rights.

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ECONOMIC, SOCIAL AND CULTURAL RIGHTS

The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights

Report of the High Commissioner

CONTENTS

		Paragraphs	Page
Introduction		1 - 4	3
I.	A HUMAN RIGHTS FRAMEWORK FOR ANALYSING THE TRIPS AGREEMENT	5 - 28	3
A.	Introduction to the TRIPS Agreement	5 - 9	3
B.	Intellectual property rights and human rights	10 - 15	5
C.	Links between human rights and the TRIPS Agreement	16 - 19	6
D.	A human rights approach to the TRIPS Agreement	20 - 28	7

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CONTENTS

		Paragraphs	Page
II.	THE TRIPS AGREEMENT AND THE RIGHT TO HEALTH	29 - 58	10
	A. Introduction	29	10
	B. States' obligations to respect, protect and fulfil the right to health	30 - 36	10
	C. Operational aspects of IP systems - medical research	37 - 41	12
	D. Operational aspects of IP systems - access to drugs	42 - 50	13
	E. The provision of HIV treatments in Brazil	51 - 58	16
III.	CONCLUSIONS AND RECOMMENDATIONS	59 - 70	18

Introduction

1. In its resolution 2000/7, the Sub-Commission for the Promotion and Protection of Human Rights requested the High Commissioner for Human Rights to undertake an analysis of the human rights impacts of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) of the World Trade Organization (WTO). In the same resolution, the Secretary-General was also requested to submit a report on the question of intellectual property rights and human rights. In relation to the Secretary-General's report, a note verbale dated 6 March was sent to States requesting information relevant to the report. That report is available as document E/CN.4/Sub.2/2001/12. Where relevant, information supplied in response to the note verbale has been included in the present report.

2. While the TRIPS Agreement could affect the enjoyment of several rights - in particular the right to food, the right to development, the human rights of indigenous peoples - the High Commissioner has decided to focus the report by examining the role of the TRIPS Agreement on the promotion and protection of the right to health. The High Commissioner has chosen the right to health as an entry point for an analysis of the TRIPS Agreement for several reasons. First, resolution 2000/7 recognizes that the TRIPS Agreement could affect the enjoyment of the right to health - in particular through its effect on access to pharmaceuticals.[1] Next, the High Commissioner views this as an opportunity to expand on work already being done by other international organizations in the area of the TRIPS Agreement and health - in particular by the World Health Organization (WHO), UNAIDS and WTO.

3. Finally, as the issue of trade agreements and health has been raised within the context of world conferences, the report can be situated within an identifiable international policy framework. Only last year, new initiatives for social development set by the General Assembly during the review of the outcome of the World Summit for Social Development invited the organizations of the United Nations system to integrate the health dimension into their policies and programmes, including through analyses of international trade agreements and trade in health goods and services (A/S-24/8/Rev.1, commitment 6, paras. 102 and 104). In the context of the special session of the General Assembly on HIV/AIDS in June 2001, the Secretary-General in his report (A/55/779, para. 48) has stated that "(g)lobally trade policy provisions need to be used more effectively to increase access to care [for people with HIV]. The availability of low-cost generic drugs needs to be expanded, in accordance with national laws and international trade agreements and with a guarantee of their quality".

4. The material for the report has been provided mainly through reports of the United Nations, the specialized agencies and WTO, as well as through consultations with some of the organizations referred to in the report.

I. A HUMAN RIGHTS FRAMEWORK FOR ANALYSING THE TRIPS AGREEMENT

A. Introduction to the TRIPS Agreement

5. The TRIPS Agreement was negotiated in the context of the Uruguay Round of multilateral trade negotiations under the General Agreement on Tariffs and Trade (GATT). The

TRIPS Agreement is the most comprehensive multilateral agreement that sets detailed minimum standards for the protection and enforcement of intellectual property rights and as a result it is a significant step in harmonizing national intellectual property (IP) systems. The Agreement is one of the agreements annexed to the Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations which came into force in 1995. This means that all members of WTO are bound by the obligations under the TRIPS Agreement.

6. The minimum standards relate to the protection of: products and processes by patents; literary, artistic, musical and other works by copyright and related rights; industrial designs; trademarks; geographical indications; layout designs of integrated circuits; and undisclosed information such as trade secrets. The Agreement sets the minimum standards - requirements for the grant of rights, the time limitations on protection, permitted exceptions to the use of rights and modes of enforcement - to be implemented by each WTO member. The permitted exceptions will be referred to in greater detail below, however, the Agreement allows member States to adopt measures to protect public health and nutrition, to promote socio-economic and technological development and to protect against the abuse of intellectual property rights in certain cases. The interpretation of these exceptions is, in large part, up to the member States. The Agreement includes special treatment for developing countries in certain circumstances, including transitional flexibility for implementation. While developed countries should have implemented the Agreement by 1996, developing countries and countries in transition had until 1 January 2000 and least developed countries have until 2006 to complete implementation. The TRIPS Agreement recognizes the economic, financial, administrative and technological constraints of the least developed countries. It therefore provides the possibility of further extension of the transitional period.[2]

7. The Agreement also makes disputes between WTO members concerning respect for the minimum standards subject to the WTO dispute settlement procedures. In the case of a dispute, a panel of specially appointed trade experts interprets the provisions of the Agreement and issues a report. A decision of the panel may be subject to appeal to the WTO Appellate Body. If a party to a dispute fails to abide by a decision, the other party can impose trade sanctions on the member in breach upon authorization by the Dispute Settlement Body.

8. Finally, the Agreement includes a built-in mechanism for review. Review of the Agreement is also possible through the biennial Ministerial Conferences. The Ministerial Conference is the highest decision-making body of WTO and it can make decisions on all matters under any of the WTO Agreements, including the TRIPS Agreement. The third Ministerial Conference was held in Seattle in 1999. This year, the fourth Ministerial Conference will be held from 9 to 13 November in Doha, Qatar, and the issue of the TRIPS Agreement will, in all likelihood, be included on the agenda.

9. It should be noted that most WTO members already had some form of intellectual property protection in place prior to the TRIPS Agreement. The key difference is that the TRIPS Agreement provides comprehensive rules governing such protection which are subject to international legal interpretation and enforcement through an effective dispute settlement mechanism.

B. Intellectual property rights and human rights

10. The starting point for a human rights analysis of TRIPS Agreement is article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the similarly worded article 27 of the Universal Declaration on Human Rights (the Universal Declaration).[3] Article 15 of the Covenant obliges States parties to respect, protect and fulfil people's cultural rights. The article identifies a need to balance the protection of both public and private interests in intellectual property. On the one hand, article 15 recognizes the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications. On the other hand, the same article recognizes the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. Taking these two aspects of article 15 together, ICESCR could be said to bind States to design IP systems that strike a balance between promoting general public interests in accessing new knowledge as easily as possible and in protecting the interests of authors and inventors in such knowledge.

11. The balance between public and private interests found under article 15 - and article 27 of the Universal Declaration - is one familiar to intellectual property law. Traditionally, States have awarded limited rights over new creations as a means of providing an incentive for innovation and for eventually ensuring public access to these creations. For example, a State may grant patents to inventors for a limited period in return for the disclosure of the invention. This ensures that the public will eventually have access to the invention, but during the period of protection, the patent holder has rights to exclude competitors from certain acts, such as making, using and selling a patented product. During this period, the patent holder has a market advantage which might allow higher prices to be charged over the technology, depending on the particular market conditions. This can be used to recoup research costs and could provide an incentive to continue inventing.

12. Consequently, there is a degree of compatibility between article 15 and traditional IP systems. However, the question essentially is where to strike the right balance.[4] Should greater emphasis be given to protecting interests of inventors and authors or to promoting public access to new knowledge? There are certain preconditions to a human rights approach to intellectual property protection which should be borne in mind.

13. First, a human rights approach requires that the public/private balance under article 15 should be struck with the primary objective of promoting and protecting human rights. This conclusion is based on the text of ICESCR itself. Article 15 should be read in conjunction with article 5 of ICESCR, which states that nothing in the Covenant can justify any act aimed at the destruction of any of its rights or freedoms or to limit a right beyond what is provided for in the Covenant.[5] In the context of article 15, this suggests that, whatever balance is struck between private and public interests in intellectual property, the balance should not work to the detriment of any of the other rights in the Covenant.[6] This position is also consistent with the Vienna Declaration and Programme of Action of the World Conference on Human Rights, which declares that "human rights are the first responsibility of Governments".[7]

14. Second, it is important to note the differing characteristics of intellectual property rights (IPRs) - copyright, patents, trademarks and so on - on the one hand, and human rights such as cultural rights on the other. Intellectual property rights are granted by the State according to well-defined criteria and so are more akin to a privilege. Those criteria are defined by national legislation. IPRs can be licensed or assigned to someone else, they can be revoked, and they eventually expire.[8] Similarly, IPRs can be - and often are - held by corporations. Human rights, on the other hand, are inalienable and universal. They are not granted by the State, they are recognized.

15. Nonetheless, intellectual property rights such as those contained in the TRIPS Agreement might be a means of operationalizing article 15, so long as the grant and exercise of those rights promotes and protects human rights. Determining whether the minimum standards contained in the TRIPS Agreement promote the enjoyment of human rights is a two-part exercise. First, the Agreement itself must be assessed for compatibility with a human rights approach. Second, the implementation of the Agreement must be assessed empirically to determine the effects of the Agreement on human rights in practice. The rest of this section focuses on assessing the TRIPS Agreement as a text from a human rights perspective.

C. Links between human rights and the TRIPS Agreement

16. Upon scrutiny, there are potential links between human rights and the TRIPS Agreement. Article 7 of the TRIPS Agreement sets out its objectives. The article states that "(t)he protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations". The objectives therefore recognize a need for balance - balance between rights and obligations of technology holders, and between the interests of producers and users of technological knowledge, with the wider objective of promoting social and economic welfare.

17. The TRIPS Agreement attempts to achieve this balance in a number of ways. First, members may take measures to protect issues relevant to ICESCR, in particular health care, nutrition and the environment. For example, under article 8, members may "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development". However, such measures are limited in the sense that they have to be consistent with the provisions of the TRIPS Agreement itself.[9] In relation to patent protection, members may exclude inventions from patentability in order to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.[10] Again, the article is limited by the proviso that such exclusions are possible so long as they are not made simply because the exploitation of the technology in question is prohibited by law.[11] Members may also exclude certain living matter from patentability, such as plants and animals, as well as methods for the treatment of humans or animals.[12]

18. Second, the TRIPS Agreement allows members to take measures to balance rights with responsibilities, indicating a degree of coherence with the balance required under article 15 of ICESCR. In relation to patents, members may authorize third parties to work the patent without

the authorization of the patent holder, subject to certain limitations.[13] This mechanism is generally referred to as a compulsory licence. The Agreement also envisages use by a government authority without the authorization of the patent holder, for example to protect the public interest. Similarly, members may take action against unfair or anti-competitive practices. According to the Principles of the Agreement, members may adopt appropriate measures to prevent the abuse of IPRs by right holders or to prevent the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.[14]

19. Third, the TRIPS Agreement encourages international cooperation. In particular, developed country members are obliged to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least developed countries[15] and to provide, on request, technical and financial cooperation in favour of developing and least developed countries.[16]

D. A human rights approach to the TRIPS Agreement

20. Protecting public health and nutrition, protecting the environment, encouraging technology transfer, advancing socio-economic development as stated in article 7 of the TRIPS Agreement, and promoting fairness and international cooperation are measures that - at least in theory - are conducive to the promotion and protection of human rights and the balance sought under article 15. They call to mind the promotion of the right to food and to health, the right to development, and the right to enjoy the benefits of scientific progress. To use an analogy, any action taken against anti-competitive practices or the abuse of IPRs or of a dominant market position could be approximated to ensuring the human rights principles of equality, equal treatment and due process. The special and differentiated treatments offered to least developed countries perhaps equates with human rights notions of affirmative action as well as international cooperation under ICESCR, the Convention on the Rights of the Child[17] and the Declaration on the Right to Development.

21. Nonetheless, recognizing the links between the standards in the TRIPS Agreement and the promotion and protection of human rights is not the same as saying that the TRIPS Agreement takes a human rights approach to intellectual property protection. The primary question is whether the TRIPS Agreement strikes a balance that is consistent with a human rights approach. A few preliminary observations are made here.

22. It is clear that while links between the promotion and protection of human rights, on the one hand, and the rights covered by the TRIPS Agreement, on the other, exist, there remain fundamental differences of approach. First of all, the overall thrust of the TRIPS Agreement is the promotion of innovation through the provision of commercial incentives. The various links with the subject matter of human rights - the promotion of public health, nutrition, environment and development - are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement. A human rights approach, on the other hand, would explicitly place the promotion and protection of human rights, in particular those in ICESCR, at the heart of the objectives of intellectual property protection, rather than only as permitted exceptions that are subordinated to the other provisions of the Agreement.[18] This is not to say that the protection of commercial objectives is necessarily incompatible with the promotion of human rights. Nonetheless, if we truly wish to

factor the promotion and protection of human rights into the objectives of the TRIPS Agreement, different ways and strategies of promoting and protecting scientific progress and its results should be explored in particular cases.

23. Second, while the Agreement identifies the need to balance rights with obligations, it gives no guidance on how to achieve this balance. On the one hand, the Agreement sets out in considerable detail the content of intellectual property *rights* - the requirements for the grant of rights, the duration of protection, the modes of enforcement. On the other hand, the Agreement only alludes to the *responsibilities* of IP holders that should balance those rights in accordance with its own objectives. The prevention of anti-competitive practices and the abuse of rights, the promotion of technology transfer, special and differential treatment for least developed countries are merely referred to - but unlike the rights it sets out, the Agreement does not establish the content of these responsibilities, or how they should be implemented. To illustrate the difference, a human rights approach might set out the minimum standards required for protection against anti-competitive practices or for the promotion of technology transfer to developing countries in much the same way as the Agreement now sets out minimum standards for the protection of patents or trademarks. Consequently, the balance identified in the TRIPS Agreement might not equate with the balance required under article 15 of ICESCR.

24. Third, like any international treaty, the TRIPS Agreement takes away a degree of autonomy from States, but it is appropriate to ask whether this affects States' abilities to promote and protect human rights, including the right to development. For example, one of the significant departures under the TRIPS Agreement from previous treaties on intellectual property rights is that the Agreement obliges WTO members to provide patent protection to cover all forms of technology, including pharmaceuticals.[19] This is a significant step. Prior to the TRIPS Agreement, States were free to decide what level of protection they would give to cover whatever forms of technology they saw as relevant to their development needs. Thus, measures to protect pharmaceuticals could be taken where national development, technological and health requirements suggested such action was beneficial. Such a position was in keeping with the Declaration on the Right to Development which declares that "States have the right and the duty to formulate appropriate national development policies that aim at the constant improvement of the well-being of the entire population and of all individuals, on the basis of their active, free and meaningful participation in development and in the fair distribution of the benefits resulting therefrom."[20] The TRIPS Agreement's obligation to provide protection for all forms of technology has an impact on States' ability to decide on development strategies.

25. Fourth, the protection contained in the TRIPS Agreement focuses on forms of protection that have developed in industrialized countries. For example, in the case of patents, the protection in the Agreement is most relevant to the protection of modern forms of technology, such as biotechnology, and most relevant to innovators situated in a selected number of industrialized countries.[21] This is reflected in the statistics, at least in the case of patents. World Bank figures relating to patent applications show an overwhelming presence of technology holders and applications in developed countries. For example, in 1997, patent applications in high-income countries numbered 2,785,420, while in East Asia and the Pacific they numbered 290,630; in the Middle East and North Africa there were only 1,716 applications and in sub-Saharan Africa only 392,959, with only 38 of those filed by residents.[22] In particular, IP protection is costly, not only to apply for, but also because of the need to pay maintenance

fees, to monitor the use of technology, and eventually to defend IPRs in the case of unauthorized use where necessary. The *Bulletin of the World Health Organization* has noted that many countries lack the technological infrastructure to benefit from costly IP systems directed to the promotion of modern technological research, thus making systems out of reach for many innovators or potential innovators in those countries.[23]

26. Further, no mention is made of the need to protect the cultural heritage and technology of local communities and indigenous peoples. While it might be the case that the negotiators of the TRIPS Agreement did not consider the protection of indigenous peoples' and local communities' knowledge, the emphasis on modern technology but not other forms of technology suggests an imbalance within the TRIPS Agreement that could have an impact on the enjoyment of human rights, in particular cultural rights. Focus on this issue has increased considerably since the adoption of the Convention on Biological Diversity in 1993.[24] Many of the forms of intellectual property protection contained in the TRIPS Agreement might be relevant to the protection of some of the knowledge of some local communities and indigenous peoples. However, there are still tensions between IP protection and the protection of the knowledge of local and indigenous communities. In particular, issues arise concerning the use of such knowledge by people outside the community without the knowledge holders' consent. Similarly, issues arise in relation to the equitable compensation for use of such knowledge where such use has led to the patenting of new knowledge. These tensions could require amendments, adaptations and additions to IP systems.

27. An overarching concern for a human rights approach to IP protection is what has become known as "TRIPS plus". WHO refers to "TRIPS plus" as a non-technical term which refers to efforts to "extend patent life beyond the 20-year TRIPS minimum; limit compulsory licensing in ways not required by TRIPS; and limit exceptions which facilitate prompt introduction of generics".[25] The term "TRIPS plus" is also used to refer to situations where countries implement TRIPS-consistent legislation before they are obliged to do so. It does not refer to the situation where States introduce new forms of IP protection such as petty patents that are not included within the minimum standards of the TRIPS Agreements but that are geared towards providing incentives for research that are appropriate to local conditions. The use of trade pressure to impose "TRIPS plus"-style IP legislation has been noted before CESCR.[26] This could lead member States to implement IP standards that do not take into account the safeguards included under the TRIPS Agreement which could lead to IP systems that are inconsistent with States' responsibilities under human rights law.

28. However, even given these differences between a human rights approach and the TRIPS Agreement, much still depends on how the TRIPS Agreement is actually implemented. The TRIPS Agreement offers significant operational flexibility and the High Commissioner urges WTO member States to use this operational flexibility in ways that would be fully compatible with the promotion and protection of human rights. In this regard, it is important to note that out of 141 States members of WTO, 111 have ratified ICESCR.

II. THE TRIPS AGREEMENT AND THE RIGHT TO HEALTH

A. Introduction

29. The following section considers issues that can arise in the implementation of the Agreement, reviewing issues relevant to the operation of IP systems in the context of the right to health. The operational issues have been grouped under two main headings - medical research and access to drugs. While IP systems can affect the right to health positively in some cases, tensions may also arise. However, the TRIPS Agreement offers member States important operational flexibility. Implementing this flexibility within the TRIPS Agreement in accordance with the standards set for the promotion of the right to health under ICESCR will assist in avoiding these tensions. The following section examines first the obligations on States to respect, protect and fulfil the right to health. It sets out some of the concerns that have arisen in the context of existing IP systems and then discusses how the flexibility inherent in the TRIPS Agreement can be used to adjust IP systems so that they are consistent with the human rights obligations of WTO members.

B. States' obligations to respect, protect and fulfil the right to health

30. Article 12 of ICESCR obliges States to respect, protect and fulfil the right of everyone to the highest attainable standard of physical and mental health.[27] CESCR has set out the content of that right in its General Comment No. 14 (E/C.12/2000/4), adopted on 11 May 2000. The General Comment sets out the content of the right, the obligations on States to respect, protect and fulfil the right, the elements of international cooperation relevant to implement the right, as well as acts constituting violations of the right. The following summary of the General Comment extracts those elements most relevant to a discussion of article 15 in the context of health. Of particular relevance are references to: the promotion of research; access to affordable treatments, in particular essential drugs; HIV/AIDS; national measures for the promotion of the right to health; clarification of international obligations; and acts that constitute violations of the right to health.

31. The right to health includes obligations on States to promote research. States are obliged to promote medical research, in particular with respect to certain categories of diseases including HIV/AIDS.[28] The obligation on States to fulfil the right to health includes the need for States to take positive measures including through fostering research into health-related areas.[29]

32. States are bound to promote the right to health through the ensuring access to affordable treatments. The right to health contains certain essential elements to be applied by States according to the prevailing national conditions. These elements include ensuring the availability, accessibility, acceptability and quality of health facilities, goods and services. The second element of accessibility includes the notion of affordability - health facilities, goods and services must be affordable for all, whether privately or publicly provided.[30] The General Comment also examines the specific steps that States should undertake in fulfilment of their obligations. Article 12 (2) (c) of ICESCR indicates that States parties to the Covenant must undertake steps necessary for "the prevention, treatment and control of epidemic, endemic, occupational and other diseases". The control of diseases refers to States' individual and joint efforts to make available relevant technologies and the promotion of strategies of infectious disease control.[31]

The right to health includes a right to facilities, goods and services, under article 12 (2) (d). This obliges States to provide equal and timely access to basic preventive, curative and rehabilitative health services and appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at the community level. The right to facilities, goods and services also includes the provision of essential drugs.[32]

33. The right to health obliges States to take into account HIV/AIDS in respecting, protecting and fulfilling the right to health. The General Comment notes that formerly unknown diseases, such as HIV/AIDS and others, as well as the rapid growth of the world population have created new obstacles to the realization of the right to health which need to be taken into account when interpreting article 12.[33]

34. The General Comment sets out some of the national measures that States must take to implement the right. It notes that, as with other rights, States are obliged to respect, protect and fulfil the right to health. It states that "(t)he obligation to respect requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees. Finally the obligation to *fulfil* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health".[34] Specifically, the General Comment states that "the obligation to *fulfil* requires States parties to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health".[35]

35. The General Comment sets out international obligations under the right to health. Specifically, States parties should recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health, taking into account the gross inequality in the health status of people, particularly between developed and developing countries.[36] States parties should ensure that the right to health is given due attention in international agreements and States parties should take steps to ensure that these instruments do not adversely impact upon the right to health.[37] Similarly, States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health.[38] The General Comment recognizes that while States are ultimately responsible for compliance with the Covenant, all members of society, including the private business sector, have responsibilities regarding the realization of the right to health.[39] States parties to the Covenant also have international obligations to "provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs" and to "take measures to prevent, treat and control epidemic and endemic diseases".[40] Further, international organizations, including WHO and WTO, should cooperate effectively with States to build on their respective expertise in relation to the right to health.[41]

36. Finally, the General Comment notes certain acts that constitute violations of the right to health. Violations of the right to health can be the result of the actions of States, or the actions of other entities insufficiently regulated by the State.[42] Violations of the obligation to protect the right to health include the failure to regulate individuals, groups or corporations so as to prevent them from violating the right to health of others.[43] Violations of the obligation to fulfil the

right to health include, amongst others, the failure to adopt or implement a national health policy designed to ensure the right to health of all; insufficient expenditure which results in non-enjoyment of the right; and the failure to take measures to reduce the inequitable distribution of health facilities, goods and services.

C. Operational aspects of IP systems - medical research

37. How compatible then is the protection and enforcement of IPRs with States' obligations to foster medical research? IPRs act as an incentive for the innovation of new technology, including pharmaceuticals. The forms of IP protection most relevant to pharmaceuticals are patents (on new medical products and processes), trademarks (covering signs distinguishing medical goods and services as coming from a particular pharmaceutical trader), and the protection of undisclosed information (in particular test data). Patents are particularly important for the pharmaceutical industry, first because the industry has to shoulder often very high costs for the testing, development and approval of drugs, and second, because pharmaceuticals are generally relatively easy to reverse-engineer and thus are open to easy copying in the absence of IP protection. It is likely that the possibility of obtaining patents on new drugs - and therefore a period of exclusivity to recover costs - acts as a major incentive to innovation in the pharmaceutical industry. While the incentive to innovate has the potential to promote the enjoyment of the right to health, this does not, ipso facto, justify the conclusion that IPRs promote respect for the right to health in all cases.

38. As IPRs are limited commercial rights, they are essentially driven towards economic reward; the objective of promoting respect for human rights would at best appear to be a secondary consideration. Two issues arise. First, as WHO has noted, the commercial motivation of IPRs means that research is directed, first and foremost, towards "profitable" disease. Diseases that predominantly affect people in poorer countries - in particular tuberculosis and malaria - still remain relatively under-researched.[44] The fact that patents create opportunities for economic reward that are optimized when market conditions are right logically leads researchers away from "unprofitable" diseases to diseases that affect people in markets where the return is likely to be greater. According to WHO, "questions remain as to whether the patent system will ensure investment for medicines needed by the poor. Of the 1,223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical disease".[45] This could mean that alternative mechanisms to patents might need to be considered by States in implementing articles 12 and 15 of ICESCR.

39. Second, again connected to the economic nature of IPRs, patents are increasingly becoming corporate assets, part of the stock of a company that reflects its competitiveness on the market. This can lead research into an innovation race. Consequently, while patenting activity is particularly high in the pharmaceutical industry, many patents cover "me-too" drugs - drugs that are just different enough to be considered novel for the purposes of patent protection, but in fact have similar effects as prior patented drugs. With "me-too" drugs, the economic gain for the patent holders is likely to be significant, but the question arises as to how the economic incentive of IPR simultaneously promotes the right to health in this situation. On the one hand, the presence of "me-too" drugs, even if patented, might lower the costs of drugs for consumers due to increased competition. On the other hand, it could result in the clogging of future research by the presence of too many patents, as well as a significant concentration of control over the

dissemination of drugs in the hands of certain corporations. This raises questions as to the effectiveness of patents as an operational mechanism for the implementation of article 15 (1) and 15 (3) of ICESCR.[46]

40. Similarly, the grant and exercise of IPRs can lead to undue restrictions on medical research which could run contrary to the requirement under article 15 of ICESCR to balance the protection of private interests with the promotion of the wide dissemination of medical knowledge. In particular, the practice of granting broad patents - an issue which has become particularly prevalent in the area of biomedical research - can lead to patents being used to block research efforts. The issue is relevant where research into a final product or process - for example, a drug - relies on several levels of innovation all of which are susceptible to IP protection. In such cases, patents on innovations from the early stages of research can be used to control and possibly block life-saving innovations that depend on the use of the first innovation.[47] Similarly, WHO has identified the situation where standards for the grant of patents can contribute to "ever-greening" - a process where minor innovations to patented innovations are themselves patented which can effectively extend the life of the patent beyond the original 20-year grant. Extending the active patent life beyond the limited period of protection could hold up other research efforts.[48] This could have implications for States' responsibilities to implement article 15 (3) of ICESCR.

41. Further, IPRs can affect the use of traditional medicines - in particular those of indigenous and local communities. Traditional medicines play an important role in the health care of all countries with up to 80 per cent of the world's population depending on traditional medications for its primary health care needs.[49] While the issues are highly complex, the High Commissioner notes two as particularly significant. First, while existing IP systems can promote the health innovations of these communities, the particular nature of this knowledge and the knowledge holders might require significant adaptation or amendments to be made to IP legislation for protection to be comprehensive. Second, traditional medicines have been appropriated, adapted and patented with little or no compensation to the original knowledge holders and without their prior consent.[50] This raises significant issues, not only in the field of the right to health, but also for the cultural rights of these communities and their members.[51] Further, it also raises the question of the effect of IP protection on the operation of the Convention on Biological Diversity, in particular its article 8 (j).

D. Operational aspects of IP systems - access to drugs

42. The starting point for a consideration of the operational aspects of IP systems with regard to access to drugs is that access to essential drugs is a human right. While the protection and enforcement of IPRs can provide a more secure environment for the transfer of technology to developing countries, it can also provide a basis for charging higher prices for drugs and for technology transfer which can restrict access for the poor. In particular, the World Bank has noted that IPRs can sometimes prevent the distribution of potential international public goods helpful to poor countries, which can seldom afford the prices charged by patent owners.[52] In the context of HIV/AIDS, the Secretary-General recently stated that "we must put care and treatment

within everyone's reach. Even a year ago few people thought that effective treatment could be brought within reach of poor people in developing countries. ... People no longer accept that the sick and dying, simply because they are poor, should be denied drugs which have transformed the lives of others who are better off".[53]

43. There are many factors that influence access to drugs. WHO has recognized four principle factors: rational selection and use of drugs, affordable prices, sustainable financing, and reliable health and supply systems.[54] The presence of IP protection over drugs can play a role in determining the affordability of drugs. However, affordability of drugs also depends on other factors such as the level of import duties, taxes, and local market approval costs. In many cases, drugs will not be protected by IPRs, either because protection was not granted in the first place or because IPRs have expired. Even where drugs are protected by IPRs, the effect of IPRs on access to drugs can be varied. However, there is evidence to suggest that the effect of patents on affordability is significant with drug prices falling sharply when generic substitutes enter a market to compete with drugs upon patent expiry.[55]

44. In the context of HIV/AIDS treatments, high prices have had a substantial impact on impeding access for sufferers. UNAIDS has recognized that high prices affect access to treatments, in particular for the 95 per cent of sufferers who are in developing countries.[56] The problem becomes particularly acute as developing countries have a high dependence on private expenditure for the purchase of medicines compared to developed countries, in spite of their higher levels of poverty.[57] According to UNAIDS, the high prices of HIV treatments are due, in part, to patent protection which allows control over their manufacture and sale.[58] The UNDP Human Development Report 2000 notes that generic production of the HIV treatment flucanazole in India has kept the price at $55 for 150 milligrammes compared with $697 in Malaysia, $703 in Indonesia and $817 in the Philippines.[59] Similarly, a report to the CESCR has noted that the AZT treatment is produced at a supply cost of $48 a month in India as compared with $239 in the United States.[60]

45. The HIV/AIDS pandemic has a significant impact on the enjoyment of human rights. Not only does it concern the enjoyment of the right to health, it is also a significant obstacle to the realization of the right to development. Looking at the health dimension: in 1999, 5.4 million people were newly infected with HIV, 34.3 million people were living with HIV/AIDS throughout the world and 2.8 million people had died from the virus. A recent report of UNAIDS illustrates the developmental dimensions of HIV/AIDS. For example, surveys note that households caring for a family member with AIDS suffer dramatic decreases of income. In education, HIV is taking its toll, first by eroding the supply of teachers who fall ill as a result of the virus, second, by health treatment eating into family education budgets, third, by adding to the pool of children who are growing up without parental support which may affect their ability to stay at school. In the agricultural sector, sickness of farm workers has resulted in a fall in agricultural output and might threaten food security. HIV is hurting business through absenteeism, lower productivity, and higher overtime costs for workers obliged to work longer hours to replace sick colleagues.[61] Indeed, the effects of HIV on the enjoyment of the right to development are so strong that the Secretary-General in his address to the African Summit described HIV/AIDS as "our biggest development challenge".[62]

46. In light of the human rights dimensions of HIV/AIDS, accessing affordable HIV treatments has itself become a human rights issue. There are several ways in which access can be improved through lowering prices, including through the exchange of price information, price competition and price negotiation with public procurement and insurance schemes, price controls, reduced duties and taxes and improved distribution efficiency, reduced distribution and dispensing costs and reduced marketing expenses. Where HIV treatments are protected by IPRs, accessing affordable drugs will depend in part on how those rights are exercised. Specifically, strategies to be considered include differential pricing, parallel importation of drugs, and generic substitution of patented drugs.

47. Differential pricing has been defined as the adaptation, in some measure, of prices to the purchasing power of consumers in different countries.[63] This could mean, for example, pricing HIV drugs at lower rates for developing countries but maintaining prices in developed country markets. The logic behind differential pricing is that higher prices can be shared in wealthy markets that can afford them, while letting poorer countries enjoy lower prices. However, one of the perceived problems with differential pricing is the possibility of low-price drugs being diverted towards wealthy markets. In the case of patented pharmaceuticals, this would lessen the opportunity to exercise IPRs as a means of recouping costs. Consequently, effective strategies to maintain higher prices in wealthy markets so that developing countries can benefit from cheaper drugs will have to be considered as part of any differential pricing strategy - possibly through some form of market segmentation. There are many ways in which market segmentation might be achieved. Where treatments are protected by IPRs, drug licensing agreements with geographical restrictions could be used so that cheaper drugs do not leak back to wealthier markets.[64] Nonetheless, many questions still remain concerning differential pricing, on the practical level. In particular, it is unclear to what extent people in wealthy countries, as well as insurance companies in wealthy countries, would accept continuing to pay high prices for drugs when lower prices are systematically being offered elsewhere. There are also questions at the practical level concerning the coexistence of differential pricing and parallel importation.

48. Another means of improving access to cheaper drugs is through parallel importation. Parallel importation has been described as importation, without necessarily having the consent of the patent holder, of a product legally marketed in another country by the patent holder or by another authorized party.[65] Thus, where a patented drug is marketed at a cheaper price in one country, another country can benefit from the cheaper drugs through importing them rather than pay the more expensive equivalent directly from the patent holder. This is possible because the patent holder's rights to control the import and export of drugs are "exhausted" once they have been placed on the market.

49. Similarly, access to affordable drugs can be improved by encouraging the production of generic substitutes. Where drugs are patent protected, generic supply must wait until expiry of the patent term. However, States may encourage generic production by taking appropriate legislative action, including through the inclusion of exceptions to patent rights which permit early testing and approval of generics prior to the expiry of the IRPs.[66] However, it is possible to produce generic substitutes even where the patent is still current. This can be achieved by a government authority issuing a compulsory licence for the patented drugs. A compulsory licence is a non-exclusive licence to produce patent rights that is granted to a third party by authorization of a government authority, irrespective of the will of the patent owner.[67] The

patent owner will receive a reasonable remuneration in return, at a rate set by the authority. Compulsory licences are generally awarded to promote the public interest or in cases of national emergency. While compulsory licences are not geared towards establishing technology partnerships between patent holders and users, they can be useful in providing a local producer the means of supplying needed drugs at cut rates. Further, the provision for the award of compulsory licences in local legislation can be an effective negotiating tool. Hesitant patent holders might be encouraged to enter voluntary licence agreements or produce needed drugs locally in order to avoid the possibility of an award of a compulsory licence.[68]

50. At the same time, IPRs such as trademarks can be a useful tool to assist consumers and medical practitioners to identify the source and quality of pharmaceuticals. Trademarks can be particularly useful to help consumers and medical practitioners ensure the source of drugs where generic drugs are allowed to be marketed without appropriate approval and testing procedures. Drugs that do not meet appropriate standards can prolong treatment periods, exacerbate conditions being treated, cause death and help create drug resistance.[69] This means that it is particularly important to ensure that trademarks are not counterfeited - that is, used on pharmaceuticals not produced by the particular trader that owns the trademark.[70]

E. The provision of HIV treatments in Brazil

51. In response to the note verbale sent on 6 March, the Government of Brazil supplied information on its HIV programme, the role played by its IP law and the impact of its health policy. The other responses - not relating specifically to the right to health - have been compiled in the report of the Secretary-General (E/CN.4/Sub.2/2001/12). According to the Brazilian Ministry of Health, there are currently 536,000 people with HIV in Brazil; there have been 196,000 notified cases of AIDS and 95,000 deaths; 85,000 people are currently receiving approved combination therapies for HIV under the Brazilian Free Distribution of AIDS Drugs for All programme.

52. Currently, the Ministry of Health is providing 12 different pharmaceuticals as the basis of the combination therapy, 7 of which are produced in Brazil - the other 5 are imported. The advantages of local production are significant. Today, the Government spends US$ 319 million on purchasing local and imported drugs to supply its HIV programme. The Ministry of Health estimates that if all those drugs had been imported, the cost to the Government would be in the range of US$ 530 million which, according to the Ministry, would make the programme unviable. It should be noted that Brazil already spends 56 per cent of the US$ 305 million spent annually on its HIV programme on the 5 imported drugs included in the 12 drugs comprising the "cocktail".

53. Of the 12 therapies, 2 are protected by patents in Brazil (Efivirenz and Nelfinavir, held by Merck Sharp & Kohme and Roche, respectively). While some of the seven drugs produced locally are protected by off-shore patents, production began before 1997 (the year in which the Brazilian patents law entered into force) so the local production does not infringe the rights of overseas patent holders. However, significant expenditures are incurred in relation to the purchase of the two patented drugs. The Ministry of Health indicates that purchase of the two patented drugs through importation has alone consumed 36 per cent of the resources of the HIV treatment budget. With the appearance of new and more effective drugs for combating AIDS,

the Ministry of Health estimates that more expensive drugs protected by patent will slowly begin to comprise the combination therapy. This development, according to the Ministry of Health, could place their HIV treatment programme at risk.

54. For this reason, the Brazilian Government has sought ways to encourage the international pharmaceutical industry to enter negotiations for the sale of drugs, taking into account the purchasing power of particular markets - in this regard, Brazil makes specific reference to the UNDP Human Development Index as an indication of relevant purchasing strength. To do this, the Government notes that it will employ all available resources in Brazilian legislation - while observing the international undertakings entered into by Brazil - to make drugs accessible to their citizens. Part of this strategy has involved the Brazilian Intellectual Property Law which came into force in 1997.

55. The Brazilian IP law allows a government authority to issue a compulsory licence where a patent holder exercises patent rights in an abusive manner, or by means of an abuse of economic power proven by an administrative or court decision. There are certain other instances where compulsory licences may be issued, including under article 71, in cases of national emergency or public interest.[71] The terms "national emergency" and "public interest" are defined in the Presidential Decree on Compulsory Licensing (1999).[72] According to the decree, "(a) national emergency is understood to be a condition of impending danger to the public, even if existing only in a part of the national territory". Further, "(t)here are considered to be within the public interest those facts, among others, related to the public health, nutrition, protection of the environment, as well as those of primordial importance to the technological or social and economic development of this country". This links closely with provisions of the TRIPS Agreement which allow for use of a patent without the authorization of the right holder in certain circumstances, including "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".[73]

56. The existence of these safeguard provisions has been helpful in improving the implementation of the Brazilian HIV treatment programme. While no compulsory licence has been issued under the Brazilian IP law, the provisions have been useful in negotiations with patent holders. The use of rights over the two patent drugs Efivirenz and Nelfinavir are cases in point. In the case of Efivirenz, the Government had begun research into the drug with the aim of achieving full capability to manufacture it locally.[74] With local manufacture in mind, a request to issue a compulsory licence for the drug had also been submitted. Since the agreement with the patent holder, the request for a compulsory licence has been put on hold, but research is continuing in case the Government finds it necessary to issue a compulsory licence in the future. In the case of Nelfinavir, negotiations for a decrease in prices are continuing. As negotiations continue, the Government is continuing research into the production of the drug and the Ministry of Health has indicated that, if negotiations do not lead to a significant decrease in price, it will consider requesting a compulsory licence so that Nelfinavir can be produced by national laboratories.

57. The results of the Brazilian strategy have been significant. In terms of the enjoyment of Brazilians' right to health, there has been a reduction in deaths due to AIDS by 50 per cent over the last four years. Further, there has been a reduction of 80 per cent in cases of hospitalization due to opportunistic diseases with a reduction in the appearance of the most serious opportunistic

diseases tuberculosis (by 60 per cent), citomegalovirus (by 54 per cent) and Kaposis sarcoma (by 38 per cent). The programme has also made economic sense. The reduction in hospitalizations has saved the Ministry of Health US$ 422 million. Moreover, costs of funding the programme are coming down. In 1999, the Ministry of Health spent US$ 336 million on drugs to reach 73,000 patients. In 2000, the Ministry spent the lower amount of US$ 319 to meet the needs of 85,000 patients. Local production of generic drugs has led to production cost cuts of, on average, 70 per cent (the reduction in the price of Zalcitabina (ddC) has been 95 per cent) and the Government has even achieved a reduction in the price of imported drugs of an average of 10 per cent. In the longer term, the programme has improved local technological and research capacity, which could enable it in the future to assist developing countries struggling with the HIV/AIDS pandemic, in particular countries in Africa.

58. On the facts that have been provided by the Government of Brazil, it is possible to say that the Brazilian case demonstrates how the provisions of the TRIPS Agreement can be implemented in ways that respect, protect and fulfil the right to health. Through careful legislative implementation of TRIPS provisions - in particular article 31 on compulsory licensing - article 71 of the Brazilian IP law supports the implementation of national health policy aimed at providing essential drugs to those who need them. Furthermore, by implementing the public health safeguards in the TRIPS Agreement, the Brazilian Government has successfully married implementation of the Agreement with its obligations under human rights law - in particular its duty to provide affordable essential drugs.

III. CONCLUSIONS AND RECOMMENDATIONS

59. What then are the obligations on States? On the one hand, the TRIPS Agreement encourages States to implement IP systems that promote economic and social development taking into account the need to balance rights with responsibilities. The Agreement allows members to take measures to protect the public interest, including the promotion of public health. Article 15 of ICESCR requires States to balance public and private interests in the design of IP protection. General Comment No. 14 on article 12 of the ICESCR indicates the measures that States should take with regard to the promotion of the right to health, including: the promotion of research; ensuring access to affordable essential drugs; the adoption of specific measures in relation to HIV/AIDS; and the promotion of international cooperation to implement the right to health.

60. Out of the 141 members of WTO that have undertaken to implement the minimum standards of IP protection in the TRIPS Agreement, 111 have ratified ICESCR. Members should therefore implement the minimum standards of the TRIPS Agreement bearing in mind both their human rights obligations as well as the flexibility inherent in the TRIPS Agreement, and recognizing that "human rights are the first responsibility of Governments". In light of this, the High Commissioner believes that implementation of the TRIPS Agreement should be characterized by the following objectives.

61. The promotion of article 15 of ICESCR. States, in implementing systems for IP protection, are encouraged to consider the most appropriate mechanisms that will promote, on the one hand, the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications and, on the other hand, the right of everyone to benefit

from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author. In this sense, **the High Commissioner encourages States to monitor the implementation of the TRIPS Agreement to ensure that its minimum standards are achieving this balance between the interests of the general public and those of the authors. The High Commissioner supports the WHO statement that "countries are advised to carefully monitor the implementation of the TRIPS Agreement in order to formulate comprehensive proposals for the future review of the TRIPS Agreement ...".**[75]

62. The promotion of the right of all to enjoy the benefits of scientific progress and its applications.[76] The design of IP systems should take into account the fact that the grant of overly broad patents can be used to block future medical research. The design of IP systems should, in calculating the difficult trade-off between public and private interests, take into consideration that the increasing tendency to grant patents for "me-too" drugs may run counter to the primary objective of IP systems to promote innovation, and focus too heavily on promoting private commercial interests. The requirements under the TRIPS Agreement for the grant of patents - novelty, inventive step and industrial applicability[77] - are open to interpretation under national legislation and each country can decide according to local conditions. Consequently, **the High Commissioner encourages interpretations of these requirements that do not lose sight of the public interest in the wide dissemination of knowledge under article 15.**

63. The promotion of the right to health. **The High Commissioner supports WHO's call that "(w)hen establishing standards of patentability for pharmaceuticals, countries should consider the implications for health of those standards".**[78]

64. The prevention of the abuse of IPRs.[79] Patents can be used to block medical research and development efforts, which calls into question their impact on economic and social welfare. Articles 8 and 40 of the TRIPS Agreement allow member States to protect against anti-competitive practices. **The High Commissioner encourages States to consider the elaboration of competition laws that prevent abuses of IPRs that lead to violations of the right to health - in particular restrictive licensing practices or the setting of high prices for essential drugs.**

65. The protection of the cultural rights of indigenous peoples and local communities.[80] The TRIPS Agreement does not refer specifically to the protection of the innovations of local and indigenous communities - a fact which indicates the Agreement is tipped in favour of the protection of modern technology but not of other forms. The report on the WHO Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine recommends that "(e)fforts should be made to utilize the flexibility in the TRIPS Agreement to promote easy access to traditional medicine for the health care needs of developing countries".[81] The report also recommends that the ways and means need to be devised and customary laws strengthened for the protection of traditional medicine knowledge from biopiracy.[82] **The High Commissioner encourages the adaptation of IP systems so that they fully take into account cultural and other rights of indigenous and local communities.**

66. The promotion of access to affordable essential drugs. Several provisions in the TRIPS Agreement offer flexibility that could be useful in promoting access to affordable essential drugs. Importantly, article 31 allows States to grant compulsory licenses for patents so long as certain conditions are fulfilled. Article 31 holds significant potential for the protection of the public interest in areas such as the promotion of the right to health. Similarly, the TRIPS Agreement does not prohibit members from allowing parallel importation of patented pharmaceuticals. Article 6 of the Agreement specifically states that the "exhaustion" of IPRs shall not be subject to dispute settlement under the Agreement. **The High Commissioner encourages member States to implement these provisions in national legislation as safeguards to protect access to essential drugs as a component of the right to health as well as other human rights.**

67. The promotion of international cooperation in the implementation of the TRIPS Agreement.[83] International cooperation is an important ingredient in the promotion and protection of human rights. The Secretary-General has emphasized the particular need for international cooperation in the context of HIV/AIDS and has proposed the establishment of a global fund dedicated to the battle against HIV/AIDS and other infectious diseases. In this context he has encouraged developing countries to exploit all options including the production and importation of "generic" drugs.[84] Article 66 (2) of the TRIPS Agreement, obliges developed country members to provide incentives to enterprises and institutions in their territories to promote technology transfer to least developed countries - a provision which could be used beneficially to promote access to affordable drugs for least developed countries. **The High Commissioner encourages developed countries to establish clear incentives to promote technology transfer and the supply of affordable drugs to developing countries.**

68. The promotion and protection of all human rights. An important aspect of the human rights approach to IP protection is the express linkage of human rights in relevant legislation. Express reference to the promotion and protection of human rights in the TRIPS Agreement would clearly link States' obligations under international trade law and human rights law and would parallel the Secretary-General's call in 1997 to mainstream human rights throughout the United Nations system. This would assist States to implement the "permitted exceptions" in the TRIPS Agreement in line with their obligations under ICESCR. To this end, the High Commissioner intends to seek observer status at the TRIPS Council. **The High Commissioner also encourages the Fourth Ministerial Meeting of the World Trade Organization in Qatar in November 2001 to consider establishing closer links between the promotion and protection of human rights and the TRIPS Agreement. In the event of a renegotiation of the Agreement, this could be achieved through an express reference to human rights in article 7.**

69. IP legislation that maintains flexibility and a balance of rights with responsibilities. **The High Commissioner joins WHO in recommending that developing countries be cautious about enacting "TRIPS plus" legislation that is more stringent than present requirements under the TRIPS Agreement without first understanding the impact of such legislation on the protection of human rights.**[85]

70. The High Commissioner also makes specific recommendations to the Sub-Commission on the Promotion and Protection of Human Rights. Section I of the present report identifies a human rights framework for analysing the TRIPS Agreement. While this report has focused on the right to health, the same analysis could be applied to the right to food, the right to development, and the rights of indigenous peoples. The analysis could also be applied to the grant and use of IPRs in relation to the human genome project. **The High Commissioner therefore recommends**:

(a) That the Sub-Commission consider requesting further reports on the impact of the TRIPS Agreement on other specific human rights;

(b) That the Sub-Commission consider recommending that the Commission on Human Rights convoke an expert seminar to consider the human rights dimensions of the TRIPS Agreement, based on the present report and any others that might be commissioned in the future.

Notes

[1] The resolution notes that "actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights in relation to, inter alia, impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food ... and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health".

[2] The TRIPS Agreement, article 66 (1).

[3] ICESCR, article 15 (1), states: "The States Parties to the present Covenant recognize the right of everyone: (a) to take part in cultural life; (b) to enjoy the benefits of scientific progress and its applications; (c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author."

[4] One way of determining the balance under human rights law is by looking at the *travaux préparatoires* - the debates that led to the eventual inclusion of the right in the Universal Declaration and ICESCR. A report (E/C.12/2000/15) submitted to the Committee on Economic, Social and Cultural Rights (CESCR), the monitoring body of the Covenant, reviewed the *travaux préparatoires* of both the Universal Declaration and ICESCR. The review concluded that, in fact, little attention was given to this issue at the time. At best, it is possible to surmise that the drafters placed a greater emphasis on promoting public interests in accessing new creations and inventions than on protecting private interests over intellectual property. The debates demonstrated a range of positions. The protection of the moral and material interests of authors was given some attention - with the focus on copyright protection, and to a lesser extent patents. However, attention was overwhelmingly placed on the right to have wide public access to innovations and creations; copyright and patents were not seen in terms of international limits on the rights of everyone to benefit from new knowledge and technology. The report further suggested that the debates concerning authors focused almost entirely on authors as individuals

and did not consider article 15 in terms of corporately held patents, or, indeed, of authors as employees of corporate rights-holders. The report also observed that it is unlikely that the drafters would have imagined the key role that intellectual property rights (IPRs) would later play in the fields of trade, development, health or food. See Maria Green "Drafting history of article 15 (1) (c) of the International Covenant on Economic, Social and Cultural Rights", 9 October 2000, in particular paragraph 45.

[5] ICESCR, article 15 (1) states that "(n)othing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights or freedoms recognized herein, or at their limitation to a greater extent than is provided for in the present Covenant".

[6] This objective of article 15 has also been recognized before the CESCR. See E/C.12/2000/12, para. 31.

[7] A/CONF.157/23, article 1.

[8] Some States recognize moral rights of authors to their works that are in fact inalienable. According to article 6 bis of the Berne Convention for the Protection of Literary and Artistic Works (1896), moral rights are referred to as follows: "Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, the said work, which would be prejudicial to his honour or reputation".

[9] The TRIPS Agreement, article 8, "Principles".

[10] Ibid., article 27 (2).

[11] Ibid.

[12] The TRIPS Agreement, article 27 (3) (b), states that members may also exclude from patentability: "(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes ..."

[13] The TRIPS Agreement, article 31.

[14] Ibid., article 8 (2), "Principles". See also article 40 in section 8, "Control of anti-competitive practices in contractual licences".

[15] Ibid., article 66 (2), "Least developed countries".

[16] Ibid., article 67, "Technical cooperation".

[17] Article 4. The Convention on the Rights of the Child has been ratified by 191 States - all but two - and is therefore the most widely ratified binding human rights treaty.

[18] A. Chapman, "Approaching intellectual property as a human right: obligations related to article 15 (1) (c)" (E/C.12/2000/12), para. 33. As Chapman has noted: "Intellectual property law should incorporate explicit human rights and ethical provisions as criteria for the evaluation of applications for patents and trademarks and develop an institutional mechanism capable of making these determinations. In most cases, patent and trademark offices are not competent to undertake such a review and are inclined to subordinate human rights considerations to an economic calculus".

[19] The TRIPS Agreement, article 27 (1) states: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application".

[20] Declaration on the Right to Development, article 2 (3). See also article 1 (2) of ICESCR which states that "All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic cooperation ..." See also article 1 (2) of the Declaration which states that the "human right to development also implies the full realization of the right to self-determination which includes ... the exercise of their inalienable right to full sovereignty over all their natural wealth and resources".

[21] For example, members are obliged to provide protection for new plant varieties either by patents or by an effective *sui generis* system or a combination of the two. The TRIPS Agreement, article 27 (3) (b).

[22] World Bank, World Development Indicators 2000, World Bank, Washington DC, table 5.12.

[23] Carlos M. Correa, "Health and Intellectual Property Rights", Bulletin of the World Health Organization, 2001, 79 (5), p. 381.

[24] See in particular article 8 (j) of the Convention which states that parties to the Convention are required to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity".

[25] "Globalization, TRIPS and access to pharmaceuticals", WHO Policy Perspectives on Medicines: WHO Medicines Strategy: 2000-2003, No. 3, March 2001 (WHO/EDM/2001.2), p. 4.

[26] Chapman, op. cit., para. 71. Chapman's paper to the Committee notes that pressure to implement TRIPS plus provisions has been applied to Brazil, Ecuador, India, Pakistan, South Africa and Thailand.

[27] Article 12 (1) states that "(t)he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standards of physical and mental health". Article 12 (2) states that "(t)he steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) the improvement of all aspects of environmental and industrial hygiene; (c) the prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) the creation of conditions which would assure to all medical service and medical attention in the event of sickness".

[28] General Comment No. 14 (2000), para. 36.

[29] Ibid., para. 37.

[30] Ibid., para. 12 (b).

[31] Ibid., para. 16.

[32] Ibid., para. 17.

[33] Ibid., para. 10.

[34] Ibid., para. 33.

[35] Ibid., para. 36.

[36] Ibid., para. 38.

[37] Ibid., para. 39.

[38] Ibid.

[39] Ibid., para 42.

[40] Ibid., paras. 43 and 44.

[41] Ibid., para. 64.

[42] Ibid., para. 48.

[43] Ibid., para. 51.

[44] P. Drahos, Human Rights, "Globalisation and intellectual property rights", paper presented at the Workshop on international trade, finance and investment and economic, social and cultural rights: the role of the Committee on Economic, Social and Cultural Rights in a Globalizing Economy, Geneva, 6 May 2000, p. 7.

[45] WHO/EDM/2001.2, op. cit., p. 5.

[46] Article 15 (3) states that "the States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity".

[47] M.A. Heller and R.S. Eisenberg, "Can Patents Defer Innovation? The Anticommons in Biomedical Research", Science, 1 May 1998, vol. 280, pp. 698-701, www.sciencemag.org

[48] WHO/EDM/2001.2, op. cit., p. 2.

[49] WHO, Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, Bangkok, 6-8 December 2000 (WHO/EDM/TRM/2001.1), p. 2.

[50] Ibid., p. 34.

[51] See, e.g., Chapman, op. cit. For example, Chapman notes the case of a small United States company that took out a US plant patent on a variety of ayahuasca (a plant with medicinal qualities) native to the Amazonian rainforest. In 1999, a coalition of environmental groups objected to the patent because it appropriated a plant that is considered sacred to many indigenous peoples from the region. The patent was voided due to lack of novelty and distinctiveness; however, the US Patent Office did not acknowledge the argument that the plant's religious value warranted an exception from patenting.

[52] World Bank, World Development Report 2000/2001, World Bank, Washington DC, p. 184.

[53] "Secretary-General proposes global fund for the fight against HIV/AIDS and other infectious diseases at African leaders summit", SG/SM/7779/Rev.1-AFR/313/Rev.1-AIDS/7/Rev.1, 26 April 2001, http://www.un.org/News/Press/docs/2001/SGSM7779R1.doc.htm

[54] WHO, "More equitable pricing for essential drugs: What do we mean and what are the issues?", background paper for the WHO-WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs, Hösbjör, Norway, 8-11 April 2001, p. 9.

[55] Watal, Jayashree, "Workshop on differential pricing and financing of essential drugs", background note prepared by Jayashree Watal, consultant to the WTO secretariat, p. 14.

[56] High prices are not the only reason behind the limited access to HIV treatments. Other reasons include limitations in infrastructure for diagnosis and treatment, lack of epidemiological data on the patterns of opportunistic diseases, gaps in the supply system and poor financing. See UNICEF/UNAIDS/WHO/EDM/MSF project, "Selected drugs used in the care of people living with HIV: sources and prices", October 2000, p. 1.

[57] Watal, op. cit., p. 9, notes that private expenditures in developing countries constitute 70-90 per cent of pharmaceutical expenditures, but only 40 per cent in developed countries.

[58] UNAIDS, Statement of the Joint United Nations Programme on HIV/AIDS (UNAIDS) at the Third WTO Ministerial Conference, Seattle, 30 November-3 December 1999 http://www.unaids.org

[59] UNDP, Human Development Report 2000, Oxford University Press, New York, 2000, p. 84.

[60] Chapman, op. cit., para. 63. It should be noted that prices for pharmaceuticals are influenced by many factors, not only the use of IPRs. Factors could be influenced by Government regulation, the exchange rate, the costs of drug testing and approval, retail overheads, the existence of tariffs and so on.

[61] UNAIDS, Report on the Global HIV/AIDS Epidemic, Geneva, June 2000, (UNAIDS/00.13E), p. 26 ff.

[62] Op. cit. at note 53.

[63] Watal, op. cit., p. 11.

[64] Ibid., p. 18.

[65] WHO/EDM/2001.2, op. cit. p. 4.

[66] Ibid., Correa, op.cit., p.381, notes that Argentina, Australia, Canada, Israel and the United States of America all have legislation allowing this exception.

[67] It should be noted that under article 31 of the TRIPS Agreement, it is still necessary to enter negotiations for authorization with the patent holder - except in the case of a national emergency or extreme urgency.

[68] For a more detailed discussion on compulsory licensing provisions in the TRIPS Agreement, see World Trade Organization, "Environment and TRIPS", Committee on Trade and Environment, 8 June 1995 (WT/CTE/W/8).

[69] WHO, Revised drug strategy: report of the secretariat A/54/17, 10 April 2001, para. 25.

[70] The TRIPS Agreement includes provisions to fight against counterfeiting, and includes provisions for international cooperation to fight counterfeiting. See in particular Part III of the TRIPS Agreement, "Enforcement of Intellectual Property Rights", and article 69 entitled "International cooperation".

[71] Intellectual Property Law (1996) Brazil, No. 9,279, article 71 of which states: "In cases of national emergency or public interest, declared in an act of the Federal Authorities, insofar as the patentee or his licensee does not meet such demand, a temporary non-exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee."

[72] Presidential Decree on Compulsory Licensing (1999) Brazil, No. 3,201, article 2.

[73] See in particular the TRIPS Agreement, article 31 (b). See also article 8.

[74] The TRIPS Agreement, article 30, states that "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." The provision is generally accepted as including the use of patents for research purposes.

[75] WHO/EDM/2001.2, op. cit., p. 6.

[76] ICESCR, article 15 (1) (b).

[77] The TRIPS Agreement, article 27 (1).

[78] WHO/EDM/2001.2, op. cit., p. 1.

[79] ICESCR, article 15 generally - i.e. the balance of private and public interests aimed at promoting the enjoyment of human rights

[80] ICESCR, article 15.

[81] WHO/EDM/TRM/2001.1, op. cit., p. 35.

[82] Ibid, p. 34. For example, this could include taking action through national legislation to prevent the acquisition of IPRs over traditional medicine by its documenting and publication or inclusion in a database. This could help prevent the patenting of traditional medicines by third parties by demonstrating that the drug or treatment is not "new".

[83] ICESCR, article 12 and article 2 (1). Article 2 (1) states that "Each State Party ... undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, ... with a view to achieving progressively the full realization of the rights recognized in the present Covenant ..."

[84] Op. cit., at note 53.

[85] WHO/EDM/2001.2, op. cit., p. 4.

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ECONOMIC, SOCIAL AND CULTURAL RIGHTS

Optional protocol to the International Covenant on Economic, Social and Cultural Rights

Note by the secretariat

1. At its fifty-second session, the Sub-Commission on the Promotion and Protection of Human Rights adopted, on 17 August 2000, resolution 2000/9 in which it requested the United Nations High Commissioner for Human Rights to organize an expert meeting on a draft optional protocol to the International Covenant on Economic, Social and Cultural Rights and to submit the report of this meeting to it at its fifty-third session. Subsequently, and pursuant also to Commission on Human Rights resolution 2000/9, paragraph 7 (b) and (f), the Office of the High Commissioner organized a workshop on the justiciability of economic, social and cultural rights, with particular reference to the draft optional protocol to the International Covenant on Economic, Social and Cultural Rights, in Geneva on 5 and 6 February, 2001.

2. The attention of the Sub-Commission is drawn to the report of the workshop, which was submitted to the Commission at its fifty-seventh session as document E/CN.4/2001/62/Add.2.

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